

## NELAC Quality Systems

Organization Name: \_\_\_\_\_

Address (Mailing): \_\_\_\_\_

Address: \_\_\_\_\_

(Physical Location): \_\_\_\_\_

Telephone: \_\_\_\_\_ Facsimile: \_\_\_\_\_

E-mail: \_\_\_\_\_ Other: \_\_\_\_\_

Personnel Interviewed:

_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Audit Location (If different): \_\_\_\_\_

Audit Date: \_\_\_\_\_

Audit Organization: \_\_\_\_\_

Auditor(s): \_\_\_\_\_

(Signatures): \_\_\_\_\_

Receipt acknowledgment by Laboratory: \_\_\_\_\_

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No	Reference	Question	Y-N-N/A	Comments
<b>5.4 - Management Requirements</b>				
1	5.0	Does the laboratory have all items identified in NELAC Chapter 5 Quality Systems available for on-site inspection or data audit?		
2	5.1.1	Does the laboratory demonstrate compliance with more stringent standards if required in a mandated test method or regulation?		
3	2.5	<p>Do the laboratory's management and all analysts ensure that all PT samples are handled (i.e., managed, analyzed, and reported) in the same manner as real environmental samples utilizing the same staff, methods as used for routine analysis of that analyte, procedures, equipment, facilities, and frequency of analysis as evidenced by the following points?</p> <p>NOTE: The AA must make a documented determination when exceptions to any of these requirements are applicable on the basis of the laboratory's routine environmental sample composition and SOPs.</p> <p>PT samples are entered into Lab's sample receipt log (Sample tracking may be initiated by laboratory personnel).</p>		
4	2.5	<p>Do the laboratory's management and all analysts ensure that all PT samples are handled in the same manner as real environmental samples?</p> <p>PT samples are diluted as instructed by PT provider and becomes the environmental sample.</p>		
5	2.5	<p>Do the laboratory's management and all analysts ensure that all PT samples are handled in the same manner as real environmental samples?</p> <p>PT sample preparation (extraction, digestion) is the same as routine environmental samples.</p>		
6	2.5	<p>Do the laboratory's management and all analysts ensure that all PT samples are handled in the same manner as real environmental samples?</p> <p>The laboratory has an SOP for the determination of low level samples. (This is to be used when PT falls below the range of laboratory's analytical method.)</p>		

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No	Reference	Question	Y-N-N/A	Comments
7	2.5	Do the laboratory's management and all analysts ensure that all PT samples are handled in the same manner as real environmental samples?  PT samples that consist of a set of individual samples (e.g. microbiology PTs) are routine samples.		
8	2.5	Do the laboratory's management and all analysts ensure that all PT samples are handled in the same manner as real environmental samples?  PT samples that consist of a set of individual samples (e.g. microbiology PTs) are routine samples.		
9	2.5	Do the laboratory's management and all analysts ensure that all PT samples are handled in the same manner as real environmental samples?  PT samples are not analyzed multiple times unless routine environmental samples are analyzed multiple times.		
10	2.5	Do the laboratory's management and all analysts ensure that all PT samples are handled in the same manner as real environmental samples?  The type, composition, concentration, and frequency of quality control samples analyzed with the PT samples is the same as with routine environmental samples.		
11	2.5	Do the laboratory's management and all analysts ensure that all PT samples are handled in the same manner as real environmental samples?  Initial and continuing calibrations are performed at the same frequency as with routine environmental samples.		
12	2.5.1.a	Does the laboratory not send any PT sample, or portion of a PT sample, to another laboratory for any analysis for which the laboratory seeks accreditation or is accredited?		
13	2.5.1.b	Does the laboratory not knowingly receive any PT sample or portion of a PT sample from another laboratory for any analysis for which the sending laboratory seeks accreditation or is accredited?		
14	2.5.1.c	Does the laboratory management and staff not communicate with any individual at another laboratory (including intralaboratory communication) concerning PT sample?		

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No	Reference	Question	Y-N-N/A	Comments
15	2.5.1.d	Does the laboratory management and staff not attempt to obtain the assigned value of any PT sample from the PT provider?		
16	2.5.2	Does the laboratory maintain copies of all written, printed and electronic records resulting from the analysis of any PT sample for 5 years or for as long as is required by the applicable regulatory program, whichever is greater?		
17	5.4.1.1	Is the laboratory, or organization of which it is part, an entity that can be held legally responsible?		
18	5.4.1.2	Does the laboratory carry out its environmental testing activities in such a way as to meet the requirements of the NELAC Standard and to satisfy the needs of the client, the regulatory authorities or organizations providing recognition?		
19	5.4.1.3	Does the laboratory management system cover work carried out in the laboratory's permanent facilities, at sites away from its permanent facilities, and/or in its associated temporary or mobile facilities?		
20	5.4.1.4	If the laboratory is part of an organization performing activities other than environmental testing, are the responsibilities of key personnel in the organization defined in order to identify potential conflicts of interest?		
21	5.4.1.4.a	Where a laboratory is part of a larger organization, are the organizational arrangements such that departments having conflicting interests, such as production, commercial marketing or financing adversely influence the laboratory's compliance with the requirements of this Standard?		
22	5.4.1.4.b	Is the laboratory able to demonstrate that it is impartial and that it and its personnel are free from any undue commercial, financial and other pressures which might influence their technical judgment?		
23	5.4.1.5.a	Does the laboratory managerial and technical personnel have the authority and resources needed to carry out their duties and to identify the occurrence of departures from the quality system or from procedures for performing environmental tests, and to initiate actions to prevent or minimize such departures?		
24	5.4.1.4.b	Does the laboratory not engage in any activities that may endanger the trust in its independence of judgment & integrity in relation to its environmental testing activities?		
25	5.4.1.5.b	Does the laboratory have processes to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work?		

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No	Reference	Question	Y-N-N/A	Comments
26	5.4.1.5.c	Does the laboratory have policies and procedures to ensure the protection of its clients' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results?		
27	5.4.1.5.d	Does the laboratory avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity?		
28	5.4.1.5.e	Does the laboratory define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between quality management technical operations and support services?		
29	5.4.1.5.f	Does the laboratory specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the environmental tests and/or calibrations?		
30	5.4.1.5.f	Does documentation include a clear description of the lines of responsibility in the laboratory and are proportioned such that adequate supervision is ensured?		
31	5.4.1.5.g	Does the laboratory provide adequate supervision of environmental testing staff, including trainees, by persons familiar with methods and procedures, purpose of each environmental test, and with the assessment of the environmental test results?		
32	5.4.1.5.h	Does the technical management, which has overall responsibility for the technical operations and the provision of the resources needed, ensure the required quality of laboratory operations?		
33	5.4.1.5.h	Does the technical director(s), however named, certify that personnel with appropriate education and/or technical background perform all tests for which the laboratory is accredited?		
34	5.4.1.5.h	Is the personnel education and technical background documented?		
35	5.4.1.5.h	Do the technical director(s) meet the requirements specified in the Accreditation Process? (see 4.1.1.1)		
36	5.4.1.5.i	Is a member of staff appointed as quality manager (however named) who, irrespective of other duties and responsibilities appointed to have defined responsibility and authority for ensuring that the quality system is implemented and followed at all times and have direct access to the highest level of management at which decisions are made on laboratory policy or resources?		
37	5.4.1.5.i.1	Does the quality manager (and/or his/her designees) serve as the focal point for QA/QC and be responsible for the oversight and/or review of quality control data;		

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No	Reference	Question	Y-N-N/A	Comments
38	5.4.1.5.i.2	Does the quality manager (and/or his/her designees) have functions independent from laboratory operations for which they can have quality assurance oversight;		
39	5.4.1.5.i.3	Does the quality manager (and/or his/her designees) able to evaluate data objectively and perform assessments with outside (e.g., managerial) influence;		
40	5.4.1.5.i.4	Does the quality manager (and/or his/her designees) have documented training and/or experience in QA/QC procedures and be knowledgeable in the quality system as defined under NELAC;		
41	5.4.1.5.i.5	Does the quality manager (and/or his/her designees) have a general knowledge of the analytical test methods for which data review is performed;		
42	5.4.1.5.i.6	Does the quality manager (and/or his/her designees) arrange for or conduct internal audits as per 5.4.13 annually; and		
43	5.4.1.5.i.7	Does the quality manager (and/or his/her designees) notify laboratory management of deficiencies in the quality system and monitor corrective action.		
44	5.4.1.5.j	Does the laboratory appoint deputies for key managerial personnel including the technical director(s) and/or quality manager?		
45	5.4.1.5.k	For purposes of qualifying for and maintaining accreditation, does each laboratory participate in a proficiency test program as outlined in Chapter 2?		
46	5.4.2.1	Has the laboratory established, implemented, & maintained a quality system, based on the required elements for NELAC Chapter 5, that is appropriate to the type, range, & volume of environmental testing activities it undertakes?		
47	5.4.2.1	Does the laboratory document its policies, systems, programs, procedures and instructions to the extent necessary to assure the quality of the environmental test results?		
48	5.4.2.1	Is the quality system documentation communicated to, understood by, available to, & implemented by the appropriate personnel?		
49	5.4.2.2	Are the laboratory's quality system policy and objectives defined in a quality manual?		
50	5.4.2.2	Are the overall objectives documented in a quality policy statement, issued under the authority of the chief executive?		

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No	Reference	Question	Y-N-N/A	Comments
51	5.4.2.2.a	Does the quality policy include the laboratory management's commitment to good professional practice and to the quality of its environmental testing in servicing its clients; The laboratory shall define and document its policies and objectives for, and its commitment to accepted laboratory practices and quality of testing services.		
52	5.4.2.2.b	Does the quality policy include the management's statement of the laboratory's standard of service;		
53	5.4.2.2.c	Does the quality policy include the objectives of the quality system; The laboratory management shall ensure that these policies and objectives are documented in a quality manual.		
54	5.4.2.2.d	Does the quality policy include a requirement that all personnel concerned with environmental testing activities within the laboratory familiarize themselves with the quality documentation and implement the policies and procedures in their work; and		
55	5.4.2.2.e	Does the quality policy include the laboratory management's commitment to compliance with this Standard.		
56	5.4.2.3	Does the quality manual, and related quality documentation, state the laboratory's policies and operational procedures established in order to meet the requirements of this Standard?		
57	5.4.2.3	When the laboratory's quality manual does not contain the necessary requirements, are these requirements addressed elsewhere in separate SOP's or policy documents?		
58	5.4.2.3	Does the quality manual list on the title page: Document title? <input type="checkbox"/> The laboratory's full name and address? <input type="checkbox"/> The name, address (if different from above), and telephone number of individual(s) responsible for the laboratory? <input type="checkbox"/> The name of the quality manager (however named); the identification of all major organizational units which are to be covered by this quality manual and the effective date of the version?		
59	5.4.2.3	Does the quality manual include or make reference to the supporting procedures including technical procedures and does it outline the structure of the documentation used in the quality system?		

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No	Reference	Question	Y-N-N/A	Comments
60	5.4.2.3.a-c	<p>Does the quality manual and related quality documentation include or reference:</p> <p>A quality policy statement, including objectives and commitments, by top management (see 5.4.2.2)?</p> <p><input type="checkbox"/> The organization and management structure of the laboratory, its place in any parent organization and relevant organizational charts?</p> <p><input type="checkbox"/> The relationship between management, technical operations, support services and the quality system?</p>		
61	5.4.2.3.d	Does the quality manual and related quality documentation include or reference procedures to ensure that all records required under this Chapter are retained, as well as procedures for control and maintenance of documentation through a document control system which ensures that all standard operating procedures (SOPs), manuals, or documents clearly indicate the time period during which the procedure or document was in force?		
62	5.4.2.3.e	Does the quality manual and related quality documentation include or reference job descriptions of key staff and reference to the job descriptions of other staff?		
63	5.4.2.3.f	Does the quality manual and related quality documentation include identification of the laboratory's approved signatories; at a minimum, the title page of the Quality Manual must have the signed and dated concurrence, (with appropriate title(s) of all responsible parties including the quality manager(s), technical director(s), and the agent who is in charge of all laboratory activities such as the laboratory director or laboratory manager?		
64	5.4.2.3.g	Does the quality manual and related quality documentation include or reference the laboratory's procedures for achieving traceability of measurements?		
65	5.4.2.3.h	Does the quality manual and related quality documentation include or reference a list of all test methods under which the laboratory performs its accredited testing?		
66	5.4.2.3.i	Does the quality manual and related quality documentation include or reference mechanisms for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work;		
67	5.4.2.3.j	Does the quality manual and related quality documentation include reference to calibration and/or verification test procedure used?		
68	5.4.2.3.k	Does the quality manual and related quality documentation include or reference procedures for handling submitted samples?		



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No	Reference	Question	Y-N-N/A	Comments
69	5.4.2.3.l	Does the quality manual and related quality documentation include or reference the major equipment and reference measurement standards used as well as the facilities and services used by the laboratory in conducting tests?		
70	5.4.2.3.m	Does the quality manual and related quality documentation include or make reference to calibration and/or verification test procedure used?		
71	5.4.2.3.n	Does the quality manual and related quality documentation include or make reference to verification practices which may include interlaboratory comparisons, proficiency testing programs, use of reference materials and internal quality control schemes?		
72	5.4.2.3.o	Does the quality manual and related quality documentation include or reference procedures to be followed for feedback and corrective action whenever testing discrepancies are detected, or departures from documented policies and procedures occur?		
73	5.4.2.3.p	Does the quality manual and related quality documentation include or reference the laboratory management arrangements for exceptionally permitting departures from documented policies and procedures or from standard specifications?		
74	5.4.2.3.q	Does the quality manual and related quality documentation include or reference procedures for dealing with complaints?		
75	5.4.2.3.r	Does the quality manual and related quality documentation include or reference procedures for protecting confidentiality (including national security concerns), and proprietary rights?		
76	5.4.2.3.s	Does the quality manual and related quality documentation include or reference procedures for audits and data review?		
77	5.4.2.3.t	Does the quality manual and related quality documentation include or reference processes/procedures for establishing that personnel are adequately experienced in the duties they are expected to carry out and are receiving any needed training?		
78	5.4.2.3.u	Does the quality manual and related quality documentation include or make reference to procedures for reporting analytical results? and,		
79	5.4.2.3.v	Does the quality manual and related quality documentation include a Table of Contents, and applicable lists of references and glossaries, and appendices.		
80	5.4.2.4	Does the quality manual define the roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with this Standard?		
81	5.4.2.5	Does the quality manager maintain the current quality manual?		

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No	Reference	Question	Y-N-N/A	Comments
82	5.4.2.6	Does the laboratory establish and maintain data integrity procedures in the quality manual, defined in detail?		
83	5.4.2.6	Does the data integrity system include: 1) data integrity training 2) signed data integrity documentation for all laboratory employees 3) in-depth, periodic monitoring of data integrity, and 4) data integrity procedure documentation.		
84	5.4.2.6	Are the data integrity procedures & the associated implementation records properly maintained & made available for assessor review?		
85	5.4.2.6	Are the data integrity procedures annually reviewed & updated by management?		
86	5.4.2.6	Are the data integrity procedures signed & dated by senior management?		
87	5.4.2.6.1	Does laboratory management provide a mechanism for confidential reporting of data integrity issues in their laboratory?		
88	5.4.2.6.2	In instances of ethical concern, does the mechanism include a process whereby laboratory management are to be informed of the need for any further detailed investigation?		
89	5.4.3.1	Does the laboratory have procedures to control all documents that form part of the laboratory's quality system?		
90	5.4.3.2.1	Are all documents issued to personnel in the laboratory as part of the quality system reviewed and approved for use by authorized personnel prior to use?		
91	5.4.3.2.1	Is there an established master list or equivalent document control procedure identifying the current revision status & distribution of documents in the quality system?		
92	5.4.3.2.1	Are the master lists or document control procedures readily available to preclude the use of invalid and/or obsolete documents?		
93	5.4.3.2.2.a	Does the document control procedure(s) adopted ensure that authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed?		
94	5.4.3.2.2.b	Does the document control procedure(s) adopted ensure that documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements?		
95	5.4.3.2.2.c	Does the document control procedure(s) adopted ensure that invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use?		

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No	Reference	Question	Y-N-N/A	Comments
96	5.4.3.2.2.d	Does the document control procedure(s) adopted ensure that obsolete documents retained for either legal or knowledge presentation purposes are suitable marked?		
97	5.4.3.2.3	Are quality system documents generated by the laboratory uniquely identified and does such identification include the date of issue and/or revision identification, page numbering, the total number of pages or a mark to signify the end of the document, and the issuing authority(ies)?		
98	5.4.3.3.1	Do the designated personnel have access to pertinent background information upon which to base their review and approval?		
99	5.4.3.3.1	Are changes to documents reviewed and approved by the same function that performed the original review, unless specifically designated otherwise?		
100	5.4.3.3.2	Where practicable, is altered or new text identified in the document or the appropriate attachments?		
101	5.4.3.3.3	If the laboratory's documentation control system allows for the amendment of documents by hand, pending the re-issue of the documents, are the procedures and authorities for such amendments defined?		
102	5.4.3.3.3	Are amendments to documents clearly marked, initialed and dated?		
103	5.4.3.3.3	Is a revised document formally re-issued as soon as practicable?		
104	5.4.3.3.4	Are procedures established to describe how changes in documents maintained in computerized systems are made and controlled?		
105	5.4.4.1	Has the laboratory established and maintained procedures for the review of requests, tenders and contracts?		
106	5.4.4.1.a	Do the policies and procedures for reviews leading to a contract for environmental testing ensure that the requirements, including the methods to be used, are adequately defined, documented and understood?		
107	5.4.4.1.b	Do the policies and procedures for reviews leading to a contract for environmental testing and/or calibration ensure that the laboratory has the capability and resources to meet the requirements?		
108	5.4.4.1.b	Is the current accreditation status of the laboratory reviewed?		
109	5.4.4.1.b	Does the laboratory inform the client of the results of the capability review if it indicates any potential conflict, deficiency, lack of appropriate accreditation status, or inability on the laboratory's part to complete the client's work?		
110	5.4.4.1.c	Do the policies and procedures for reviews leading to a contract for environmental testing ensure that the appropriate environmental test method is selected and capable of meeting the clients' requirements?		

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No	Reference	Question	Y-N-N/A	Comments
111	5.4.4.1	Are any differences between the request or tender & the contract resolved before any work commences?		
112	5.4.4.2	Are records of reviews, including any significant changes maintained?		
113	5.4.4.2	Are records also maintained of pertinent discussions with a client relating to the client's requirements or the results of the work during the period of execution of the contract? Note: For review of routine and other simple tasks, the date and the identification (e. g. the initials) of the person in the laboratory responsible for carrying out the contracted work are considered adequate. For repetitive routine tasks, the review need be made only at the initial enquiry stage or on granting of the contract for on-going routine work performed under a general agreement with the client, provided that the client's requirements remain unchanged. For new, complex or advanced environmental testing and/or calibration tasks, a more comprehensive record should be maintained. (5.4.4.2).		
114	5.4.4.3	Does the review cover any work that is subcontracted by the laboratory?		
115	5.4.4.4	Is the client informed of any deviation from the contract?		
116	5.4.4.5	If a contract needs to be amended after work has commenced, is the same contract review process repeated and any amendments communicated to all affected personnel?		
117	5.4.4.5	Are any contract amendments communicated to all affected personnel?		
118	5.4.5.1	Does the laboratory submit any subcontract work for testing covered under NELAP only to a laboratory accredited under NELAP for the tests to be performed or one that meets applicable statutory & regulatory requirements for performing the tests & submitting the results of tests performed.		
119	5.4.4.5	If a contract needs to be amended after work has commenced, does the laboratory report any suspensions, revocations, or voluntary withdrawals of accreditation to the client?		
120	5.4.5.1	When a laboratory subcontracts work, does the laboratory clearly identify in final reports non-NELAP accredited work?		
121	5.4.5.1	Is the laboratory performing the subcontracted work indicated in the final report and non-NELAP accredited work clearly identified?		
122	5.4.5.2	Does the laboratory advise the client of the subcontracting arrangement in writing and, when appropriate, gain the approval of the client, preferably in writing?		

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No	Reference	Question	Y-N-N/A	Comments
123	5.4.5.3	Is the laboratory responsible to the client for the subcontractor's work, except in the case where the client or a regulatory authority specifies which subcontractor is to be used?		
124	5.4.5.4	Does the laboratory maintain a register of all subcontractors that it uses for environmental tests and maintain a record of the evidence of compliance with 5.4.5.1?		
125	5.4.6.1	Does the laboratory have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the environmental tests?		
126	5.4.6.1	Do procedures exist for the purchase, reception, & storage of reagents & consumable materials relevant for the environmental tests?		
127	5.4.6.2	Does the laboratory ensure that purchased supplies, reagents and consumable materials that affect quality are not used until they have been inspected or otherwise verified as complying with requirements defined in the methods for the environmental tests concerned?		
128	5.4.6.2	Does the laboratory ensure that supplies & services comply with specified requirements?		
129	5.4.6.2	Does the laboratory maintain records of actions taken to check compliance with these requirements?		
130	5.4.6.3	Do purchasing documents for items affecting the quality of laboratory output contain data describing the services and supplies ordered?		
131	5.4.6.3	Are these purchasing documents reviewed & approved for technical content prior to release?		
132	5.4.6.4	Does the laboratory maintain records of these evaluations and list those (suppliers) approved?		
133	5.4.6.4	Does the laboratory evaluate suppliers of critical consumables, supplies and services which affect the quality of environmental testing?		
134	5.4.7	Does the laboratory afford clients or their representative's cooperation to clarify the client's request and monitor the laboratory's performance in relation to the work performed?		
135	5.4.8	Does the laboratory have a policy and procedure for the resolution of complaints received from clients or other parties?		
136	5.4.8	Does the laboratory maintain records of all such complaints and of the investigations & actions taken by the laboratory?		
137	5.4.9.1	Does the laboratory have a policy and procedures that are implemented when any aspect of its environmental testing, or the results of this work, does not conform to its own procedures or the agreed requirements of the client?		

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No	Reference	Question	Y-N-N/A	Comments
138	5.4.9.1	Do the policy and procedures ensure that the responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports, as necessary) are defined and taken when nonconforming work is identified?		
139	5.4.9.1.a	Do the policy and procedures for nonconforming work ensure that the responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports and calibration certificates, as necessary) are defined and taken when nonconforming work is identified?		
140	5.4.9.1.b	Do the policy and procedures for nonconforming work ensure that an evaluation of the significance of the nonconforming work is made?		
141	5.4.9.1.c	Do the policy and procedures for nonconforming work ensure that corrective actions are taken immediately, together with any decision about the acceptability of the nonconforming work?		
142	5.4.9.1.d	Do the policy and procedures for nonconforming work ensure that where the data quality is or may be impacted, the client is notified and the work may be recalled?		
143	5.4.9.1.e	Do the policy and procedures for nonconforming work ensure that the responsibility for authorizing the resumption of work is defined?		
144	5.4.9.2	Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, are the corrective action procedures given in 5.4.10 promptly followed?		
145	5.4.10.1	Does the laboratory have an established policy and procedure and designated appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the quality system or technical operations have been identified?		
146	5.4.10.2	Does the procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem?		
147	5.4.10.3	Where corrective action is needed, does the laboratory identify potential corrective actions?		
148	5.4.10.3	Does the laboratory select and implement the action(s) most likely to eliminate the problem and prevent recurrence?		
149	5.4.10.3	Are corrective actions made to a degree appropriate to the magnitude and the risk of the problem?		
150	5.4.10.3	Does the laboratory document and implement any required changes resulting from corrective action investigations?		

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No	Reference	Question	Y-N-N/A	Comments
151	5.4.10.4	Does the laboratory monitor the results to ensure that the corrective actions taken is effective?		
152	5.4.10.5	Where the identification of nonconformances or departures casts doubts on the laboratory's compliance with its own policies and procedures, or on its compliance with this Standard, does the laboratory ensure that the appropriate areas of activity are audited in accordance with 5.4.13 as soon as possible?		
153	5.4.10.6.a	In addition to providing acceptance criteria and specific protocols for corrective actions in the Method SOPs (see 5.5.4.1.1), does the laboratory implement general procedures to be followed to determine when departures from documented policies, procedures and quality control have occurred?		
154	5.4.10.6.a.1-3	Do these corrective action procedures include the following: <input type="checkbox"/> Identify the individual(s) responsible for assessing which QC data type? <input type="checkbox"/> Identify individual(s) responsible for initiating and/or recommending corrective actions? <input type="checkbox"/> Define how the analyst shall treat a data set if the associated QC measurement are unacceptable? <input type="checkbox"/> Specify how out-of-control situations & subsequent corrective actions are to be documented? <input type="checkbox"/> Specify procedures for management & the QA officer to review corrective action reports?		
155	5.4.10.6.b	To the extent possible, are sample test results reported only if QC measures are acceptable?		
156	5.4.10.6.b	Does the laboratory report samples with the appropriate laboratory defined data qualifier(s) when a quality control measure associated with that sample analysis was found to be out of control and the data is to be reported?		
157	5.4.11.1	Are needed improvements and potential sources of nonconformance, either technical or concerning the quality system, identified?		
158	5.4.11.1	If preventative action is required, are action plans developed, implemented, & monitored to reduce the occurrence of nonconformances & to take advantage of opportunities for improvement?		
159	5.4.11.2	Do procedures for preventive actions include the initiation of such actions and application of controls to ensure that they are effective?		
160	5.4.12	Does the laboratory retain all original observations, calculations and derived data, calibration records and a copy of the test report for a minimum of five years?		

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No	Reference	Question	Y-N-N/A	Comments
161	5.4.12	Does the laboratory maintain a record system to suit its particular circumstances and comply with any applicable regulations?		
162	5.4.12	Does the record system produce unequivocal, accurate records which document all laboratory activities?		
163	5.4.12	If the laboratory's clients specify that a sample will be used for evidentiary purposes, does the laboratory have a written SOP for how it will carry out legal chain of custody (for example, ASTM D 4840- 95 and Manual for the Certification of Laboratories Analyzing Drinking Water, March 1997, Appendix A)?		
164	5.4.12.1.1	Does the laboratory establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records?		
165	5.4.12.1.1	Do quality records include reports from internal audits and management reviews as well as records of corrective and preventive actions? (Records may be in any media, such as hard copy or electronic media).		
166	5.4.12.1.2	Are all records legible?		
167	5.4.12.1.2	Are all records retained in such a way that they are readily retrievable?		
168	5.4.12.1.2	Are all records stored in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss?		
169	5.4.12.1.2	Has retention times of records been established?		
170	5.4.12.1.3	Are all records held secure and in confidence?		
171	5.4.12.1.4	Does the laboratory have procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of records stored electronically?		
172	5.4.12.1.5	Does the record keeping system allow historical reconstruction of all laboratory activities that produced the analytical data?		
173	5.4.12.1.5	Is the history of the sample readily understood through the documentation (including interlaboratory transfers of samples and/or extracts?		
174	5.4.12.1.5.a	Do the records include the identity of personnel involved in sampling, sample receipt, preparation, or testing?		
175	5.4.12.1.5.b	Is all information relating to the laboratory facilities equipment, analytical test methods, and related laboratory activities, such as sample receipt, sample preparation, or data verification documented?		
176	5.4.12.1.5.c	Does the record keeping system facilitate the retrieval of all working files and archived records for inspection and verification purposes, e.g., set format for naming electronic files?		



# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
177	5.4.12.1.5.d	Are all changes to records signed or initialed by responsible staff?		
178	5.4.12.1.5.d	Is the reason for the signature or initials clearly indicated in the records such as "sampled by," "prepared by," or "reviewed by"?		
179	5.4.12.1.5.e	Are all generated data except those that are generated by automated data collection systems, recorded directly, promptly and legibly in permanent ink?		
180	5.4.12.1.5.f	Are entries in records changed so as not to be obliterated by methods such as erasures, overwritten files or markings?		
181	5.4.12.1.5.f	Are all corrections to record-keeping errors made by one line marked through the error?		
182	5.4.12.1.5.f	Is the individual making the change to electronically maintained records identified?		
183	5.4.12.1.5.f	Does the individual making the correction sign (or initial) and date the correction?		
184	5.4.12.1.5.f	Are entries to electronically maintained records changed so as to not erase or overwrite the files?		
185	5.4.12.2.1	Does the laboratory retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report for a defined period?		
186	5.4.12.2.1	Do the records for each environmental test contain sufficient information to facilitate identification of factors affecting the uncertainty and enable the environmental test to be repeated under conditions as close as possible to the original?		
187	5.4.12.2.1	Do the records include identity of personnel responsible for the sampling, performance of the environmental test, & checking the results?		
188	5.4.12.2.2	Are observations, data and calculations identifiable to the specific task?		
189	5.4.12.2.2	Are observations, data and calculations recorded at the time they are made?		
190	5.4.12.2.3	When mistakes occur in records, is each mistake crossed out, not erased, made illegible or deleted, and is the correct value entered alongside?		
191	5.4.12.2.3	Does the laboratory take equivalent measures to avoid loss or change of original data in records stored electronically?		
192	5.4.12.2.3	When corrections are due to reasons other than transcription errors, does the laboratory document the reason for the correction?		

## NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
193	5.4.12.2.3	Are all alterations to records signed or initialed by the person making the correction?		
194	5.4.12.2.4.a	Are all records (including those pertaining to test equipment), certificates and reports safely stored, held secure and in confidence to the client?		
195	5.4.12.2.4.a	Are all NELAP-related records available to the accrediting authority?		
196	5.4.12.2.4.b	Are all records, including those specified in 5.4.12.2.5 retained for a minimum of five years from generation of the last entry in the records?		
197	5.4.12.2.4.b	Is all information necessary for the historical reconstruction of data maintained by the laboratory?		
198	5.4.12.2.4.b	Are records which are stored only on electronic media supported by the hardware and software necessary for their retrieval?		
199	5.4.12.2.4.c	Do records that are stored or generated by computers or personal computers have hard copy or write-protected backup copies?		
200	5.4.12.2.4.d	Has the laboratory established a record management system for control of laboratory notebooks, instrument logbooks, standards logbooks, and records for data reduction, validation, storage and reporting?		
201	5.4.12.2.4.e	Is access to archived information documented with an access log?		
202	5.4.12.2.4.e	Are records protected against fire, theft, loss, environmental deterioration, vermin and, in the case of electronic records, electronic or magnetic sources?		
203	5.4.12.2.4.f	Does the laboratory have a plan to ensure that the records are maintained or transferred according to the clients' instructions (see 4.1.8.e) in the event that a laboratory transfers ownership or goes out of business? (In cases of bankruptcy, appropriate regulatory and state legal requirements concerning laboratory records must be followed.)		
204	5.4.12.2.5.1.a	Does the laboratory maintain a record of all procedures to which a sample is subjected while in the possession of the laboratory pertaining to sample preservation including appropriateness of sample container and compliance with holding time requirement?		
205	5.4.12.2.5.1.b	Does the laboratory maintain a record of all procedures to which a sample is subjected while in the possession of the laboratory pertaining to sample identification, receipt, acceptance or rejection and log-in?		
206	5.4.12.2.5.1.c	Does the laboratory maintain a record of all procedures to which a sample is subjected while in the possession of the laboratory pertaining to sample storage and tracking including shipping receipts, sample transmittal forms, (chain of custody form);		

# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
207	5.4.12.2.5.1.d	Does the laboratory maintain a record of all procedures to which a sample is subjected while in the possession of the laboratory pertaining to the laboratory shall have documented procedures for the receipt and retention of samples, including all provisions necessary to protect the integrity of samples?		
208	5.4.12.2.5.2.a-h	<p>In addition to documenting all the above-mentioned activities, are the following retained:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> All original raw data, whether hard copy or electronic, for calibrations, samples and quality control measures, including analysts' work sheets and data output records? (chromatograms, strip charts, and other instrument response readout records);</li> <li><input type="checkbox"/> A written description or reference to the specific test method used which includes a description of the specific computational steps used to translate parametric observations into a reportable analytical value?</li> <li><input type="checkbox"/> Copies of final reports?</li> <li><input type="checkbox"/> Archived SOPs?</li> <li><input type="checkbox"/> Correspondence relating to laboratory activities for a specific project?</li> <li><input type="checkbox"/> All corrective action reports, audits and audit responses?</li> <li><input type="checkbox"/> Proficiency test results and raw data? and,</li> <li><input type="checkbox"/> Results of data review, verification, and cross-checking procedures?</li> </ul>		

# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
209	5.4.12.2.5.3.a-n	<p>Do analytical records include the following essential information associated with an analysis, such as strip charts, tabular printouts, computer data files, analytical notebooks, and run logs</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Laboratory sample ID code?</li> <li><input type="checkbox"/> Date of analysis and time of analysis is required if the holding time is 72 hours or less or when time critical steps are included in the analysis, e.g., extractions, and incubations?</li> <li><input type="checkbox"/> Instrumentation identification and instrument operating conditions/parameters (or reference to such data)?</li> <li><input type="checkbox"/> Analysis type?</li> <li><input type="checkbox"/> All manual calculations, e.g., manual integrations? and,</li> <li><input type="checkbox"/> Analyst's or operator's initials/signature?</li> <li><input type="checkbox"/> Sample preparation including cleanup, separation protocols, incubation periods or subculture, ID codes, volumes, weights, instrument printouts, meter readings, calculations, reagents?</li> <li><input type="checkbox"/> Sample analysis?</li> <li><input type="checkbox"/> Standard and reagent origin, receipt, preparation, and use?</li> <li><input type="checkbox"/> Calibration criteria, frequency and acceptance criteria?</li> <li><input type="checkbox"/> Data and statistical calculations, review, confirmation, interpretation, assessment, and reporting conventions?</li> <li><input type="checkbox"/> Quality control protocols and assessment?</li> <li><input type="checkbox"/> Electronic data security, software documentation and verification, software and hardware audits, backups, and records of any changes to automated data entries?</li> <li><input type="checkbox"/> Method performance criteria including expected quality control requirements?</li> </ul>		
210	5.4.12.2.5.4.a-c	Are the following administrative records maintained; Personnel qualifications, experience and training records and Records of demonstration of capability for each analyst and A log of names, initials and signatures for all individuals who are responsible for signing or initialing any laboratory record?		
211	5.4.13.1	Does the laboratory periodically, in accordance with a predetermined schedule and procedure, and at least annually, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the quality system and this Standard?		
212	5.4.13.1	Does the internal audit program address all elements of the quality, including the environmental testing activities?		
213	5.4.13.2	When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's environmental test results, does the laboratory take timely corrective action, and notify clients in writing if investigations show that the laboratory results may have been affected.		

# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
214	5.4.13.2	Does the laboratory specify in its Quality Manual the time frame for notifying a client of events that cast doubt on the validity of the test results?		
215	5.4.13.1	Are such audits carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited?		
216	5.4.13.1	Does personnel not audit their own activities except when it can be demonstrated that an effective audit will be carried out?		
217	5.4.13.1	Is it the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management?		
218	5.4.13.2	Does the laboratory notify clients promptly, in writing, of any event such as the identification of defective measuring or test equipment that casts doubt on the validity of results given in any test report or test certificate or amendment to a report or certificate?		
219	5.4.13.3	Is the area of activity audited, the audit findings and corrective actions that arise from them recorded?		
220	5.4.13.3	Does the laboratory management ensure that corrective actions are discharged within the appropriate & agreed time frame as indicated in the quality manual and/or SOP's?		
221	5.4.13.4	Do follow-up audit activities verify and record the implementation and effectiveness of the corrective action taken?		
222	5.4.14.1	In accordance with a predetermined schedule and procedure, does the laboratory's executive management periodically and at least annually conduct a review of the laboratory's quality system and environmental testing activities to ensure their continuing suitability and effectiveness, and introduce necessary changes or improvements?		
223	5.4.14.1.a-j	Does the management review take account of: <input type="checkbox"/> The suitability of policies and procedures? <input type="checkbox"/> Reports from managerial and supervisory personnel? <input type="checkbox"/> The outcome of recent internal audits? <input type="checkbox"/> Corrective and preventive actions? <input type="checkbox"/> Assessments by external bodies? <input type="checkbox"/> The results of interlaboratory comparisons or proficiency tests? <input type="checkbox"/> Changes in the volume and type of the work? <input type="checkbox"/> Client feedback? <input type="checkbox"/> Complaints? <input type="checkbox"/> Other relevant factors, such as quality control activities, resources and staff training?		
224	5.4.14.2	Does management ensure that those actions are carried out within an appropriate and agreed timescale?		

# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
225	5.4.14.2	Does the laboratory have a procedure for review by management and does it maintain records of review findings and actions?		
226	5.4.14.2	Are findings from management reviews and the actions that arise from them recorded?		
227	5.4.15	Does the laboratory, as part of their overall internal auditing program, insure that a review is conducted with respect to any evidence of inappropriate actions or vulnerabilities related to data integrity?		
228	5.4.15	Is discovery of potential issues handled in a confidential manner until such time as a follow up evaluation, full investigation, or other appropriate actions have been completed and the issues clarified?		
229	5.4.15	Is all documentation of these investigation and actions taken maintained for at least five years?		
230	5.4.15	Does documentation of the investigations include any disciplinary actions involved, corrective actions taken, and all appropriate notifications of clients?		
231	5.4.15	Are all investigations that result in finding of inappropriate activity documented?		

# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
<b>5.5 - Technical Requirements</b>				
232	5.5.1.1.a-g	Does the laboratory determine correctness and reliability of the environmental tests include contributions from: <ul style="list-style-type: none"> <li><input type="checkbox"/> Human factors (5.5.2)</li> <li><input type="checkbox"/> Accommodation and environmental conditions (5.5.3)?</li> <li><input type="checkbox"/> Environmental test methods and method validation (5.5.4)?</li> <li><input type="checkbox"/> Equipment (5.5.5)?</li> <li><input type="checkbox"/> Measurement traceability (5.5.6)?</li> <li><input type="checkbox"/> Sampling (5.5.7)?</li> <li><input type="checkbox"/> The handling of samples (5.5.8)?</li> </ul>		
233	5.5.1.2	Does the laboratory take account of the factors that contribute to the total uncertainty of measurement in developing environmental test methods and procedures, in the training and qualification of personnel, and in the selection and calibration of the equipment it uses?		
234	5.5.2.1	Does laboratory management ensure the competence of all who operate specific equipment, perform environmental tests, evaluate results, and sign test reports?		
235	5.5.2.1	When using staff that are undergoing training, is appropriate supervision provided?		
236	5.5.2.1	Are personnel performing specific tasks qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required?		
237	5.5.2.1	Does the laboratory have sufficient personnel with the necessary education, training, technical knowledge and experience for their assigned functions?		
238	5.5.2.1	Are all personnel responsible for complying with all quality assurance/quality control requirements that pertain to their organizational/ technical function?		
239	5.5.2.1	Does each technical staff member have a combination of experience and education to adequately demonstrate a specific knowledge of their particular function and a general knowledge of laboratory operations, test methods, quality assurance/quality control procedures and records management?		
240	5.5.2.2	Does the management formulate goals with respect to the education, training and skills of the laboratory personnel?		
241	5.5.2.2	Does the laboratory have a policy and procedures for identifying training needs and providing training of personnel?		
242	5.5.2.2	Is the training program relevant to the present and anticipated tasks of the laboratory?		

# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
243	5.5.2.3	Does the laboratory use personnel who are employed by, or under contract to, the laboratory?		
244	5.5.2.3	Where contracted and additional technical and key support personnel are used, does the laboratory ensure that such personnel are supervised and competent and that they work in accordance with the laboratory's quality system?		
245	5.5.2.4	Does the laboratory maintain current job descriptions for all personnel who manage, perform, or verify work affecting the quality of the environmental tests?		
246	5.5.2.5	Does management authorize specific personnel to perform particular types of sampling, environmental testing, to issue test reports, to give opinions and interpretations and to operate particular types of equipment?		
247	5.5.2.5	Does the laboratory maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel?		
248	5.5.2.5	Are the records readily available and do they include the date on which authorization and/or competence is confirmed?		
249	5.5.2.5	Do the records include demonstrated proficiency for each laboratory test method, such as the criteria outlined in 5.5.4.2.2 for chemical testing?		
250	5.5.2.5	Are records on the relevant qualifications, training, skills and experience of the technical personnel maintained by the laboratory?		
251	5.5.2.6.a	Does laboratory management define the minimal level of qualification, experience and skills necessary for all positions in the laboratory. In addition to education and/or experience, basic laboratory skills such as using a balance, colony counting, aseptic or quantitative techniques shall be considered?		
252	5.5.2.6.b	Does laboratory management ensure that all technical laboratory staff have demonstrated capability in the activities for which they are responsible. Such demonstration shall be documented. (See Appendix C);		
253	5.5.2.6.c.1	Does laboratory management maintain documentation on file that demonstrates that each employee has read, understood, and is using the latest version of the laboratory's in-house quality documentation, which relates to his/her job responsibilities?		
254	5.5.2.6.c.2	Does laboratory management provide for and document training courses or workshops on specific equipment, analytical techniques or laboratory procedures?		



# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
255	5.5.2.6.c.3	Does laboratory management ensure that the training file contains a certification that technical personnel have read, understood and agreed to perform the most recent version of the test method (the approved method or standard operating procedure as defined by the laboratory document control system, 5.4.2.3.d) and documentation of continued proficiency by at least one of the following once per year: <ul style="list-style-type: none"> <li><input type="checkbox"/> Acceptable performance of a blind sample (single blind to the analyst)?</li> <li><input type="checkbox"/> An initial measurement system evaluation or another demonstration of capability?</li> <li><input type="checkbox"/> At least four consecutive laboratory control samples with acceptable levels of precision and accuracy?</li> <li><input type="checkbox"/> If these cannot be performed, analysis of authentic samples with results statistically indistinguishable from those obtained by another trained analyst?</li> </ul>		
256	5.5.2.6.d	Does laboratory management document all analytical and operational activities of the laboratory?		
257	5.5.2.6.e	Does laboratory management supervise all personnel employed by the laboratory?		
258	5.5.2.6.f	Does laboratory management ensure that all sample acceptance criteria (Section 5.5.8) are verified and that samples are logged into the sample tracking system and properly labeled and stored?		
259	5.5.2.6.g	Does laboratory management document the quality of all data reported?		
260	5.5.2.7	Is data integrity training provided as a formal part of new employee is it provided on an annual basis for all current employees?		
261	5.5.2.7	Are topics covered documented in writing and provided to all trainees?		
262	5.5.2.7	Do key topics covered during training include organizational mission and its relationship to the critical need for honesty and full disclosure in all analytical reporting, how and when to report data integrity issues, and record keeping?		
263	5.5.2.7	Are employees required to understand that any infractions of the laboratory data integrity procedures will result in a detailed investigation that could lead to very serious consequences including immediate termination, debarment or civil/criminal prosecution?		
264	5.5.2.7	Does the initial data integrity training and the annual refresher training have a signature attendance sheet or other form of documentation that demonstrates all staff have participated and understand their obligations related to data integrity?		

## NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
265	5.5.2.7	Do senior managers acknowledge their support of these procedures by: <input type="checkbox"/> Upholding the spirit and intent of the organization's data integrity procedures? <input type="checkbox"/> Effectively implementing the specific requirements of the procedures?		
266	5.5.2.7	Are specific examples of breaches of ethical behavior discussed including improper data manipulations, adjustments of instrument time clocks, and inappropriate changes in concentrations of standards?		
267	5.5.2.7	Does training include discussion regarding all data integrity procedures, data integrity training documentation, in-depth data monitoring and data integrity procedure documentation?		
268	5.5.2.7	Does data integrity training require emphasis on the importance of proper written narration on the part of the analyst with respect to those cases where analytical data may be useful, but are in one sense or another partially deficient?		
269	5.5.3.1	Are laboratory facilities for environmental testing, including but not limited to energy sources, lighting and environmental conditions, such as to facilitate correct performance of the environmental tests?		
270	5.5.3.1	Does the laboratory ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement?		
271	5.5.3.1	Is particular care taken when sampling and environmental tests are undertaken at sites other than a permanent laboratory facility?		
272	5.5.3.1	Are the technical requirements for accommodation and environmental conditions that can affect the results of environmental tests documented?		
273	5.5.3.2	Is due attention paid, for example, to biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned?		
274	5.5.3.2	Are environmental tests and calibrations stopped when the environmental conditions jeopardize the results of the environmental tests?		
275	5.5.3.2	In instances where monitoring or control of any of the mentioned items are specified in a test method or by regulation, does the laboratory meet and document adherence to the laboratory facility requirements?		
276	5.5.3.2	Does the laboratory monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results?		

# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
277	5.5.3.3	Is there effective separation between neighboring areas in which there are incompatible activities including culture handling or incubation areas and volatile organic chemicals handling areas?		
278	5.5.3.3	Are measures taken to prevent cross-contamination?		
279	5.5.3.4	Does the laboratory determine the extent of control based on its particular circumstances?		
280	5.5.3.4	Is access to and use of areas affecting the quality of the environmental tests controlled?		
281	5.5.3.5	Are measures taken to ensure good housekeeping in the laboratory?		
282	5.5.3.5	Are special procedures prepared where necessary?		
283	5.5.3.6.a-e	Do work areas provide the following: <input type="checkbox"/> Access and entryways to the laboratory? <input type="checkbox"/> Sample receipt area(s)? <input type="checkbox"/> Sample storage area(s)? <input type="checkbox"/> Chemical and waste storage area(s)? <input type="checkbox"/> Data handling and storage area(s)?		
284	5.5.4.1	Does the laboratory use appropriate methods and procedures for all environmental tests and/or calibrations within its scope?		
285	5.5.4.1	Does the laboratory have instructions on the use and operation of all relevant equipment, and on the handling and preparation of samples where the absence of such instructions could jeopardize the results of environmental tests?		
286	5.5.4.1	Are all instructions, standards, manuals and reference data relevant to the work of the laboratory kept up to date and made readily available to personnel?		
287	5.5.4.1	Do deviations from environmental test methods occur only if the deviation has been documented, technically justified, authorized, and accepted by the client?		
288	5.5.4.1.1	Does the laboratory maintain SOPs that accurately reflect all phases of current laboratory activities such as assessing data integrity, corrective actions, handling customer complaints, and all test methods?		
289	5.5.4.1.1.b	If the test methods are copies of published methods are any changes or selected options in the methods are documented and included in the methods manual?		
290	5.5.4.1.1.c	Are copies of all SOPs accessible to all personnel?		
291	5.5.4.1.1.d	Are the SOPs organized?		
292	5.5.4.1.1.e	Does each SOP clearly indicate the effective date of the document, the revision number and the signature(s) of the approving authority?		

# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
293	5.5.4.1.1.f	Do the laboratory SOPs contain sufficient information to perform the tests?		
294	5.5.4.1.1.f	Do the documents need to be supplemented or rewritten as internal procedures, if the documents are written in a way that they can be used as written?		
295	5.5.4.1.1.f	Are changes, including the use of selected option documented and included in the laboratory's methods manual?		
296	5.5.4.1.2.a	Does the laboratory have and maintain an in-house methods manual(s) for each accredited analyte or test method?		
297	5.5.4.1.2.b	Does the laboratory clearly indicate in its methods manual any modifications made to the referenced test method and describe any changes or clarifications where the referenced test method is ambiguous or provides insufficient detail?		
298	5.5.4.1.2.b.1-23	<input type="checkbox"/> Does each test method include or reference where applicable: <input type="checkbox"/> Identification of the test method? <input type="checkbox"/> Applicable matrix or matrices? <input type="checkbox"/> Detection limit? <input type="checkbox"/> Scope and application, including components to be analyzed? <input type="checkbox"/> Summary of the test method? <input type="checkbox"/> Definitions? <input type="checkbox"/> Interferences? <input type="checkbox"/> Safety? <input type="checkbox"/> Equipment and supplies? <input type="checkbox"/> Reagents and standards? <input type="checkbox"/> Sample collection, preservation, shipment and storage? <input type="checkbox"/> Quality control? <input type="checkbox"/> Calibration and standardization? <input type="checkbox"/> Procedure? <input type="checkbox"/> Data analysis and calculations? <input type="checkbox"/> Method performance? <input type="checkbox"/> Pollution prevention? <input type="checkbox"/> Data assessment and acceptance criteria for quality control measures? <input type="checkbox"/> Corrective actions for out-of-control data? <input type="checkbox"/> Contingencies for handling out-of-control or unacceptable data? <input type="checkbox"/> Waste management? <input type="checkbox"/> References? <input type="checkbox"/> Any tables, diagrams, flowcharts and validation data?		

# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
299	5.5.4.2	Does the laboratory use methods for environmental testing, including methods for sampling, which meet the needs of the client and which are appropriate for the environmental tests it undertakes?		
300	5.5.4.2.1.a	Are methods published in international, regional or national standards used if possible?		
301	5.5.4.2.1.a	Does the laboratory ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so?		
302	5.5.4.2.1.a	When necessary, is the standard supplemented with additional details to ensure consistent application?		
303	5.5.4.2.1.b	When the use of specific methods for a sample analysis are mandated or requested, are only those methods used?		
304	5.5.4.2.1.c	When the client does not specify the method to be used or where methods are employed that are not required, are the methods fully documented and validated?		
305	5.5.4.2.1.c	When the client does not specify the method to be used or where methods are employed that are not required, are the methods used available to the client and other recipients of the relevant reports?		
306	5.5.4.2.1.c	Does the laboratory select appropriate methods that have been published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment?		
307	5.5.4.2.1.c	Are laboratory-developed methods or methods adopted by the laboratory used only if they are appropriate for the intended use and if they are validated?		
308	5.5.4.2.1.c	Is the client informed as to the method chosen?		
309	5.5.4.2.1.d	Does the laboratory inform the client when the method proposed by the client is considered to be inappropriate or out of date?		
310	5.5.4.2.2	Does the laboratory confirm that it can properly operate all methods before introducing the environmental tests?		
311	5.5.4.2.2	If the method changes, does the laboratory confirm that it can properly operate the method before introducing the environmental tests?		
312	5.5.4.2.2.a	Prior to acceptance and institution of any method, is a satisfactory demonstration of method capability performed?		
313	5.5.4.2.2.a	Is this demonstration done in an applicable and available clean matrix sample of a matrix in which no target analytes or interferences are present at concentrations that impact the results of a specific test method?		
314	5.5.4.2.2.a	For analytes which do not lend themselves to spiking, is the demonstration of capability performed using quality control samples?		

# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
315	5.5.4.2.2.b	Is a continuing demonstration of method performance, as per the quality control requirements in Appendix D (such as laboratory control samples) performed thereafter?		
316	5.5.4.2.2.c	In cases where a laboratory analyzes samples using a method that has been in use by the laboratory before July 1999, and there have been no significant changes in instrument type, personnel or method, the continuing demonstration of method performance and the analyst's documentation of continued proficiency is deemed acceptable. Does the laboratory have records on file to demonstrate that a DOC is not required?		
317	5.5.4.2.2.d	In all cases, are the appropriate forms such as the Certification Statement (Appendix C) completed and retained by the laboratory to be made available upon request?		
318	5.5.4.2.2.d	Is all associated supporting data necessary to reproduce the analytical results summarized in the Certification Statement retained by the laboratory?		
319	5.5.4.2.2.e	Is a demonstration of capability completed each time there is a change in instrument type, personnel, or method?		
320	5.5.4.2.2.f	In laboratories with a specialized "work cell(s)" (a group consisting of analysts with specifically defined tasks that together perform the test method), does the group as a unit meet the criteria of NELAC 5.5.4.2.2.A-E, and is this demonstration of capability fully documented?		
321	5.5.4.2.2.g	When a work cell(s) is employed, and the members of the cell change, do the new employee(s) work with experienced analyst(s) in that area of the work cell where they are employed?		
322	5.5.4.2.2.g	Does this new work cell demonstrate acceptable performance through acceptable documented continuing performance checks each time that membership in the work cell changes?		
323	5.5.4.2.2.g	If the entire work cell is changed/replaced, does the new work cell perform the demonstration of capability?		
324	5.5.4.2.2.g	Is the demonstration repeated if the four preparation batches following the change in personnel have a failure of any batch acceptance criteria, e.g., method blank and laboratory control sample?		
325	5.5.4.2.2.h	When a work cell(s) is employed, is the performance of the group linked to the training record of the individual members of the work cell?		
326	5.5.4.3	Is the introduction of environmental test methods developed by the laboratory for its own use a planned activity?		
327	5.5.4.3	Is the introduction of environmental test methods assigned to qualified personnel equipped with adequate resources?		

## NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
328	5.5.4.3	Are plans updated as development proceeds and is there effective communication amongst all personnel involved?		
329	5.5.4.4	Does this agreement include a clear specification of the client's requirements and the purpose of the environmental test?		
330	5.5.4.4	When it is necessary to use methods not covered by standard methods, are these methods subject to agreement with the client?		
331	5.5.4.4	Is the method developed validated appropriately before use?		
332	5.5.4.5.2	Does the laboratory validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their published scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use?		
333	5.5.4.5.2	Is the validation as extensive as is necessary to meet the needs of the given application or field of application?		
334	5.5.4.5.2	Has the laboratory recorded the results obtained, the procedure used for the validation, & a statement as to whether the method is fit for intended use?		
335	5.5.4.5.2	Are the minimum requirements the initial test method evaluation requirements given in Appendix C.3 of this chapter?		
336	5.5.4.5.3	Does the range and accuracy of the values obtainable from validated methods (e. g. the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object), as assessed for the intended use, relevant to the clients' needs?		
337	5.5.4.6.1	Does the laboratory have and apply procedures for estimating uncertainty of measurement?		
338	5.5.4.6.1	In cases that are metrologically and statistically valid, calculation of uncertainty of measurement, does the laboratory at least attempt to identify all the components of uncertainty and make a reasonable estimation?		
339	5.5.4.6.1	Is a reasonable estimation based on knowledge of the performance of the method and on the measurement scope?		
340	5.5.4.6.1	In cases where the nature of the test method preclude rigorous, metrologically and statistically valid, calculation of uncertainty of measurement, and does the laboratory ensure that the form of reporting of the result does not give a wrong impression of the uncertainty?		
341	5.5.4.6.1	Does the reasonable estimation of uncertainty make use of previous experience & validation data?		

# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
342	5.5.4.6.2	When estimating the uncertainty of measurement, are all uncertainty components which are of importance in the given situation taken into account using appropriate methods of analysis?		
343	5.5.4.7.1	Are calculations and data transfers subject to appropriate checks in a systematic manner?		
344	5.5.4.7.1.a	Does the laboratory establish SOPs to ensure that the reported data are free from transcription and calculation errors?		
345	5.5.4.7.1.b	Has the laboratory established SOPs to ensure that all quality control measures are reviewed, and evaluated before data are reported?		
346	5.5.4.7.1.c	Does the laboratory have established SOPs addressing manual calculations including manual integrations?		
347	5.5.4.7.2.a	When computers, automated equipment, or microprocessors are used for the acquisition, processing, recording, reporting, storage or retrieval of environmental test, does the laboratory ensure that computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use;		
348	5.5.4.7.2.b	When computers, automated equipment, or microprocessors are used for the acquisition, processing, recording, reporting, storage or retrieval of environmental test, does the laboratory ensure that procedures are established and implemented for protecting the data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing?		
349	5.5.4.7.2.c	When computers, automated equipment, or microprocessors are used for the acquisition, processing, recording, reporting, storage or retrieval of environmental test, does the laboratory ensure that computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of environmental test data?		
350	5.5.4.7.2.d	When computers, automated equipment, or microprocessors are used for the acquisition, processing, recording, reporting, storage or retrieval of environmental test, does the laboratory ensure that it establishes and implements appropriate procedures for the maintenance of security of data including the prevention of unauthorized access to, and the unauthorized amendment of, computer records.		
351	5.5.5.1	Is the laboratory furnished with all items of sampling, measurement and test equipment required for the correct performance of the environmental tests (including sampling, preparation of samples, processing and analysis of environmental data)?		



# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
352	5.5.5.1	In those cases where the laboratory needs to use equipment outside its permanent control, does it ensure that the requirements of this Standard are met?		
353	5.5.5.2	Is the equipment and the software used for testing; capable of achieving the accuracy required and does it comply with specifications relevant to the environmental tests concerned?		
354	5.5.5.2	Is equipment checked and/or calibrated before use to ensure that it meets the laboratory's specification requirements and complies with the relevant standard specifications?		
355	5.5.5.2	Before being placed into service, is equipment (including that used for sampling) calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications?		
356	5.5.5.2.1.a	Is all support equipment maintained in proper working order?		
357	5.5.5.2.1.a	Are the records of all repair and maintenance activities including service calls kept?		
358	5.5.5.2.1.b	Are the results of support equipment calibration within the specifications required of the application for which this equipment is used?		
359	5.5.5.2.1.b	Is all support equipment calibrated or verified at least annually, using NIST traceable references when available, over the entire range of use?		
360	5.5.5.2.1.b.1-2	Are the results of support equipment calibration within the specifications required of the application for which this equipment is used as follows or <input type="checkbox"/> Is the equipment removed from service until repaired or <input type="checkbox"/> Does the laboratory maintain records of established correction factors to correct all measurements?		
361	5.5.5.2.1.c	Are raw data records retained to document support equipment performance?		
362	5.5.5.2.1.d	Prior to use on each working day, are balances, ovens, refrigerators, freezers, and water baths checked in the expected use range, with NIST traceable references where commercially available?		
363	5.5.5.2.1.d	Is the acceptability for use or continued use determined by the needs of the analysis or application for which the equipment is being used?		
364	5.5.5.2.1.e	Are mechanical volumetric dispensing devices including burettes (except Class A glassware) checked for accuracy on at least a quarterly use basis?		

# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
365	5.5.5.2.1.e	Do glass microliter syringes come with a certificate attesting to established accuracy or is the accuracy initially demonstrated and documented by the laboratory?		
366	5.5.5.2.1.f	For chemical tests, is the temperature, cycle time, and pressure of each run of autoclaves documented by the use of appropriate chemical indicators or temperature recorders and pressure gauges?		
367	5.5.5.2.2	Is initial instrument calibration used directly for quantitation and continuing instrument calibration verification used to confirm the continued validity of the initial calibration?		
368	5.5.5.2.2	If more stringent standards or requirements are included in a mandated test method or by regulation, does the laboratory demonstrate that such requirements are met?		
369	5.5.5.2.2	If it is not apparent which standard is more stringent, are the requirements of the regulation or mandated test method followed?		
370	5.5.5.2.2.1.a	Are the details of the initial instrument calibration procedures including calculations, integrations, acceptance criteria and associated statistics included or referenced in the test method SOP. When initial instrument calibration procedures are referenced in the test method, then the referenced material must be retained by the laboratory and be available for review.		
371	5.5.5.2.2.1.b	Are sufficient raw data records retained to permit reconstruction of the initial instrument calibration, e.g., calibration date, test method, instrument, analysis date, each analyte name, analyst's initials or signature; concentration and response, calibration curve or response factor; or unique equation or coefficient used to reduce instrument responses to concentration.		
372	5.5.5.2.2.1.c	Are sample results quantitated from the initial instrument calibration and may not be quantitated from any continuing instrument calibration verification unless otherwise required by regulation, method, or program.		
373	5.5.5.2.2.1.d	Are all initial instrument calibrations verified with a standard obtained from a second manufacturer or lot if the lot can be demonstrated from the manufacturer as prepared independently from other lots. Traceability shall be to a national standard, when available.		
374	5.5.5.2.2.1.e	Is the criteria for the acceptance of an initial instrument calibration established, e.g., correlation coefficient or relative percent difference. The criteria used must be appropriate to the calibration technique employed.		

# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
375	5.5.5.2.2.1.f	Is the lowest calibration standard the lowest concentration for which quantitative data are to be reported (see Appendix C.) Any data reported below the lower limit of quantitation should be considered to have an increased quantitative uncertainty and shall be reported using defined qualifiers or flags or explained in the case narrative.		
376	5.5.5.2.2.1.g	Is the highest calibration standard the highest concentration for which quantitative data are to be reported (see Appendix C.) Any data reported above this highest standard should be considered to have an increased quantitative uncertainty and shall be reported using defined qualifiers or flags or explained in the case narrative.		
377	5.5.5.2.2.1.h.1-4	For instrument technology (such as ICP or ICP/MS) with validated techniques from manufacturers or methods employing standardization with a zero point and a single point calibration standard: <ul style="list-style-type: none"> <li><input type="checkbox"/> Are the zero point and single point calibration analyzed prior to the analysis of samples?</li> <li><input type="checkbox"/> Are a zero point and single point calibration standard analyzed with each analytical batch?</li> <li><input type="checkbox"/> Is a standard corresponding to the lowest quantitation level analyzed with each analytical batch and must meet established acceptance criteria?</li> <li><input type="checkbox"/> Is the linearity is verified at a frequency established by the method and/or the manufacturer?</li> </ul>		
378	5.5.5.2.2.1.h	Are measured concentrations outside the working range reported with defined qualifiers or flags or explained in the case narrative?		
379	5.5.5.2.2.1.h	Are the lowest calibration standards above the limit of detection with the exception: of the following shall occur for instrument technology (such as ICP or ICP/MS) with validated techniques from manufacturers or methods employing standardization with a zero point and a single point calibration standard?		
380	5.5.5.2.2.1.i	If the initial instrument calibration results are outside established acceptance criteria, corrective actions are performed and all associated samples reanalyzed or if reanalysis of the samples is not possible, data associated with an unacceptable initial instrument calibration is reported with appropriate data qualifiers?		
381	5.5.5.2.2.1.j	If a reference or mandated method does not specify the number of calibration standards, is the minimum number is two, (one of which must be at the limit of quantitation) not including blanks or a zero standard with the noted exception of instrument technology for which it has been established by methodologies and procedures that a zero and a single point standard are appropriate for calibrations (see 5.5.5.2.2.1 h)?		

# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
382	5.5.5.2.2.1.j	Does the laboratory have a standard operating procedure for determining the number of points for establishing the initial instrument calibration?		
383	5.5.5.3	Are up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) readily available for use by the appropriate laboratory personnel?		
384	5.5.5.3	Is all equipment properly maintained, inspected and cleaned?		
385	5.5.5.3	Are maintenance procedures documented?		
386	5.5.5.3	Is equipment operated by authorized personnel?		
387	5.5.5.4	Is each item of equipment and its software used for environmental testing and calibration that is significant to the result, uniquely identified, when practicable?		
388	5.5.5.5	Are records maintained of each major item of equipment and its software significant to the environmental tests performed?		
389	5.5.5.5.a-j	Do the maintenance records include at least the following: <ul style="list-style-type: none"> <li><input type="checkbox"/> The identity of the item of equipment and its software?</li> <li><input type="checkbox"/> The manufacturer's name, type identification, and serial number or other unique identification?</li> <li><input type="checkbox"/> Checks that equipment complies with the specification (see 5.5.5.2)?</li> <li><input type="checkbox"/> The current location?</li> <li><input type="checkbox"/> The manufacturer's instructions, if available, or reference to their location?</li> <li><input type="checkbox"/> Dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration?</li> <li><input type="checkbox"/> The maintenance plan, where appropriate, and maintenance carried out to date; documentation on all routine and non-routine maintenance activities and reference material verifications?</li> <li><input type="checkbox"/> Any damage, malfunction, modification or repair to the equipment?</li> <li><input type="checkbox"/> Date received and date placed in service (if available)?</li> <li><input type="checkbox"/> If available, condition when received (e.g. new, used, reconditioned)?</li> </ul>		
390	5.5.5.6	Does the laboratory have procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration?		

## NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
391	5.5.5.7	Is equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, taken out of service?		
392	5.5.5.7	Is the equipment isolated to prevent its use or clearly labeled or marked as being out of service, until it has been repaired and shown by calibration or test to perform correctly?		
393	5.5.5.7	Does the laboratory examine the effect of the defect or departure from specified limits on previous environmental tests and institute the "Control of nonconforming work" procedure as required by 5.4.9?		
394	5.5.5.8	Whenever practicable, is all equipment under the control of the laboratory and requiring calibration labeled, coded or otherwise identified to indicate the status of calibration including the date when last calibrated and the date or expiration criteria when recalibration is due?		
395	5.5.5.9	When, for whatever reason, equipment goes outside the direct control of the laboratory, does the laboratory ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service?		
396	5.5.5.10	When an initial calibration is not performed on the day of analysis, is the validity of the initial calibration verified prior to sample analyses by continuing instrument calibration verification with each analytical batch?		
397	5.5.5.10.a	Are the details of the continuing instrument calibration procedure, calculations and associated statistics included or referenced in the test method SOP?		
398	5.5.5.10.b	Is the calibration verified for each compound, element, or other discrete chemical species, except for multi-component analytes such as Aroclors, Total Petroleum Hydrocarbons, or Toxaphene where a representative chemical related substance or mixture can be used?		
399	5.5.5.10.c.1-4	Is instrument calibration verification performed: At the beginning and end of each analytical batch (except, if an internal standard is used, only one verification needs to be performed at the beginning of the analytical batch) or Whenever it is expected that the analytical system may be out of calibration or might not meet the verification acceptance criteria or If the time period for calibration or the most previous calibration verification has expired or For analytical systems that contain a calibration verification requirement?		
400	5.5.5.10.e	If the continuing instrument calibration verification results obtained are outside established acceptance criteria, are corrective actions performed?.		

## NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
401	5.5.5.10.e	If routine corrective action procedures fail to produce a second consecutive (immediate) calibration verification within acceptance criteria, then does the laboratory demonstrate acceptable performance after corrective action with two consecutive calibration verifications, or perform a new initial instrument calibration?		
402	5.5.5.10.e.1-2	When the acceptance criteria for the continuing calibration verification are exceeded high, i.e., high bias, and there are associated samples that are non-detects, then those non-detects may be reported. Otherwise the samples affected by the unacceptable calibration verification shall be reanalyzed after a new calibration curve has been established, evaluated and accepted?		
403	5.5.5.10.e.1-2	When the acceptance criteria for the continuing calibration verification are exceeded low, i.e., low bias, those sample results may be reported if they exceed a maximum regulatory limit/decision level. Otherwise the samples affected by the unacceptable verification shall be reanalyzed after a new calibration curve has been established, evaluated and accepted?		
404	5.5.5.11	Where calibrations give rise to a set of correction factors, does the laboratory have procedures to ensure that copies (e.g. in computer software) are correctly updated?		
405	5.5.5.12	Is test equipment, including both hardware and software, safeguarded from adjustments which would invalidate the test results?		
406	5.5.6.1	Does the laboratory have an established program and procedure for the calibration of its equipment which includes balances, thermometers, and control standards?		
407	5.5.6.1	Does this program include a system for selecting, using, calibrating, checking, controlling and maintaining the following items when used to perform environmental tests?		
408	5.5.6.1	Is all equipment used for environmental tests, including equipment for subsidiary measurements (e. g. for environmental conditions) having a significant effect on the accuracy or validity of the result of the environmental test, or sampling, calibrated before being put into service and on a continuing basis?		
409	5.5.6.2.1	Does the laboratory ensure that the equipment used can provide the uncertainty of measurement needed?		
410	5.5.6.2.1	Is the overall program of calibration and/or verification and validation of equipment designed and operated so as to ensure that measurements made by the laboratory are traceable to national standards of measurement?		

# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
411	5.5.6.2.2	Does the laboratory provide satisfactory evidence of correlation of results, for example by participation in a suitable program of interlaboratory comparisons, proficiency testing or independent analysis.		
412	5.5.6.2.2	Where traceability of measurements to SI units is not possible or not relevant, are the same requirements for traceability to, for example, certified reference materials, agreed methods and/or consensus standards are required?		
413	5.5.6.3.1	Does the laboratory have a program and procedure for the calibration of its reference standards?		
414	5.5.6.3.1	Are reference standards calibrated by a body that can provide traceability to national standards?		
415	5.5.6.3.1	Are reference standards calibrated before and after any adjustment?		
416	5.5.6.3.1	Are reference standards of measurement held by the laboratory (such as class S or equivalent weights or traceable thermometers) used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated?		
417	5.5.6.3.2	Are reference materials, where commercially available, traceable to SI units of measurement, or to certified reference materials?		
418	5.5.6.3.2	Are internal reference materials checked as far as is technically and economically practicable?		
419	5.5.6.3.3	Are checks carried out to maintain confidence in the status of reference, primary, transfer or working standards and reference materials according to defined procedures and schedules?		
420	5.5.6.3.4	Does the laboratory have procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity?		
421	5.5.6.4	Do documented procedures exist for the purchase, reception and storage of consumable materials used for the technical operations of the laboratory?		
422	5.5.6.4.a	Does the laboratory retain records for all standards, reagents, reference materials and media including: <ul style="list-style-type: none"> <li><input type="checkbox"/> The manufacturer/vendor?</li> <li><input type="checkbox"/> The manufacturer's Certificate of Analysis or purity (if supplied)?</li> <li><input type="checkbox"/> The date of receipt?</li> <li><input type="checkbox"/> Recommended storage conditions?</li> <li><input type="checkbox"/> An expiration date after which the material shall not be used unless its reliability is verified by the laboratory?</li> </ul>		

# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
423	5.5.6.4.b	Are original containers (as provided by the manufacturer or vendor) labeled with an expiration date?		
424	5.5.6.4.c	Are records maintained on reagent, standard, and reference material preparation?		
425	5.5.6.4.c	Do the preparation records indicate: <input type="checkbox"/> Traceability to purchased stocks or neat compounds? <input type="checkbox"/> Reference to the method of preparation? <input type="checkbox"/> Date of preparation? <input type="checkbox"/> Expiration date? <input type="checkbox"/> Preparer's initials?		
426	5.5.6.4.d	Do all containers of prepared standards, and reference materials bear a unique identifier and expiration date and are linked to the documentation requirements in 5.5.6.4.c?		
427	5.5.6.4.e	Are procedures in place to ensure prepared reagents meet the requirements of the test method?		
428	5.5.6.4.f	Do all containers of prepared reagents used bear a preparation date?		
429	5.5.6.4.f	Is an expiration date placed on a container or documented elsewhere as indicated in the laboratory's quality manual or SOP?		
430	5.5.7.1	Does the laboratory have a sampling plan and procedure for sampling when it carries out sampling of substances, materials or products for subsequent environmental testing?		
431	5.5.7.1	Is the sampling plan as well as the sampling procedure available at the location where sampling is undertaken?		
432	5.5.7.1	Are sampling plans, whenever reasonable, based on appropriate statistical methods?		
433	5.5.7.1	Does the sampling process address the factors to be controlled to ensure the validity of the environmental test and calibration results?		
434	5.5.7.1	Where subsampling (as in obtaining sample aliquots from a submitted sample) is carried out as part of the test method, does the laboratory use documented procedures and appropriate techniques to obtain representative sub-samples?		
435	5.5.7.2	Are client required deviations, additions or exclusions from the documented sampling procedure, recorded in detail with the appropriate sampling data?		
436	5.5.7.2	Are client required deviations included in all documents containing environmental test results?		
437	5.5.7.2	Are any required deviations, additions, or exclusions (to sampling plans) communicated to the appropriate personnel?		



# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
438	5.5.7.3	Do the records include: <input type="checkbox"/> The sampling procedure used? <input type="checkbox"/> The identification of the sampler? <input type="checkbox"/> The environmental conditions (if relevant)? Diagrams or other equivalent means to identify the sampling location (as necessary)? <input type="checkbox"/> The statistics the sampling procedures are based upon; (if appropriate)?		
439	5.5.7.3	Does the laboratory have procedures for recording data and operations relevant to sampling that forms part of the environmental testing that is undertaken?		
440	5.5.8.1	Does the laboratory have procedures for the transportation, receipt, handling, protection, storage, retention, and/or disposal of samples, including all provisions necessary to protect the integrity of the sample, and to protect the interests of the laboratory and the client, including: <input type="checkbox"/> Handling? <input type="checkbox"/> Protection? <input type="checkbox"/> Storage? <input type="checkbox"/> Retention and/or disposal of samples, including all provisions necessary to protect the integrity of the sample?		
441	5.5.8.2	Does the laboratory have a system for identifying samples?		
442	5.5.8.2	Is the sample identification retained throughout the life of the sample in the laboratory?		
443	5.5.8.2	Is the sample identification system designed and operated so as to ensure that samples cannot be confused physically or when referred to in records or other documents?		
444	5.5.8.2	Does the sample identification system, if appropriate, accommodate a sub-division of groups of samples and the transfer of samples within and from the laboratory?		
445	5.5.8.2.a	Does the laboratory have a documented system for uniquely identifying the samples to be tested, to ensure that there can be no confusion regarding the identity of such samples at any time?		
446	5.5.8.2.a	Does the system include identification for all samples, sub-samples and subsequent extracts and/or digestates?		
447	5.5.8.2.a	Does the laboratory assign a unique identification (ID) code to each sample container received in the laboratory? Note: The use of container shape, size or other physical characteristic, such as amber glass, or purple top, is not an acceptable means of identifying the sample.		

# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
448	5.5.8.2.b	Does the laboratory sample code maintain an unequivocal link with the unique field ID code assigned each container?		
449	5.5.8.2.c	Is the laboratory ID code placed on the sample container as a durable label?		
450	5.5.8.2.d	Is the laboratory ID code entered into the laboratory records and is it the link that associates the sample with related laboratory activities such as sample preparation?		
451	5.5.8.3	Upon receipt of the sample(s) is the condition, including any abnormalities or departures from normal or specified conditions as described in the environmental test method, recorded?		
452	5.5.8.3	Does the laboratory consult with the client for further instruction when there is doubt as to the suitability of a sample for environmental test, or when a sample does not conform to the description provided, or the environmental test or calibration required is not specified in sufficient detail?		
453	5.5.8.3	Are such discussions with the client (on suitability of the sample for testing) recorded?		
454	5.5.8.3.1.a.1	Are all samples which require thermal preservation accepted only if the arrival temperature is either within 2°C of the required temperature or the method specified range or for samples with a specified temperature of 4°C, samples with a temperature ranging from just above the freezing temperature of water to 6°C shall be acceptable. Note: Samples that are hand delivered to the laboratory on the same day that they are collected may not meet this criteria. In these cases, the samples shall be considered acceptable if there is evidence that the chilling process has begun such as arrival on ice.		
455	5.5.8.3.1.a.2	Does the laboratory implement procedures for checking chemical preservation using readily available techniques, such as pH or free chlorine, prior to or during sample preparation or analysis?		

# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
456	5.5.8.3.1.a.3.i-iii	<p>When the following conditions are not met, does the laboratory perform a chlorine residual check on microbiological samples from chlorinated water systems:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Sufficient sodium thiosulfate is added to each container to neutralize at minimum 5 mg/l of chlorine for drinking water and 15mg/l of chlorine for wastewater samples or</li> <li><input type="checkbox"/> One container from each batch of laboratory prepared containers or lot of purchased ready-to-use containers is checked to ensure efficacy of the sodium thiosulfate to 5 mg/l chlorine or 15mg/l chlorine as appropriate and the check is documented or</li> <li><input type="checkbox"/> Chlorine residual is checked in the field and actual concentration is documented with sample submission?</li> </ul>		
457	5.5.8.3.1.b	Are the results of all preservation checks recorded?		
458	5.5.8.3.1.c.1-2 i-ii	<p>If the sample does not meet the sample receipt acceptance criteria, does the laboratory either:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Retain correspondence and/or records of conversations concerning the final disposition of rejected samples or</li> <li><input type="checkbox"/> Fully document any decision to proceed with the analysis of samples not meeting acceptance criteria by noting the condition of these samples on the chain of custody or transmittal form and laboratory receipt documents or adding a qualifier to the analysis data on the final report?</li> </ul>		
459	5.5.8.3.1.d	Does the laboratory utilize a permanent chronological record such as a log book or electronic database to document receipt of all sample containers?		
460	5.5.8.3.1.d.1.i-iv	<p>Is the sample receipt log used to record the following:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Client/project name?</li> <li><input type="checkbox"/> Date and time of laboratory receipt?</li> <li><input type="checkbox"/> Unique laboratory ID code?</li> <li><input type="checkbox"/> Signature or initials of the person making the entries? Note: The placement of the laboratory ID number on the sample container is not considered a permanent record. (5.5.8.3.1.d.2)</li> </ul>		
461	5.5.8.3.1.d.2	During the log-in process, is sample collection information unequivocally linked to the log record or included as a part of the log?		
462	5.5.8.3.1.d.2.i	Is the field ID code which identifies each container linked to the laboratory ID code in the sample receipt log?		
463	5.5.8.3.1.d.2.iii	Is the requested analyses (including applicable approved test method numbers) linked to the laboratory ID code?		
464	5.5.8.3.1.d.2.iv	Are any comments resulting from inspection for sample rejection linked to the laboratory ID code?		

# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
465	5.5.8.3.1.d.2	If sample collection information is recorded/documented elsewhere, are the records a part of the laboratory's permanent records, easily retrievable upon request and readily available to individuals who will process the sample?		
466	5.5.8.3.1.d.2.ii	Are the date and time of sample collection linked to the sample container and to the date and time receipt in the laboratory		
467	5.5.8.3.1.e	Is all documentation, such as memos or transmittal forms that are transmitted to the laboratory by the sample transmitter retained?		
468	5.5.8.3.1.f	If chain of custody procedures are used, is a complete chain of custody record form maintained?		
469	5.5.8.3.2	Does the laboratory have a written sample acceptance policy that clearly outlines the circumstances under which samples shall be accepted or rejected?		
470	5.5.8.3.2	Is this sample acceptance policy available to sample collection personnel?		
471	5.5.8.3.2	Are data from any samples which does not meet the sample acceptance criteria flagged in an unambiguous manner clearly defining the nature and substance of the variation?		
472	5.5.8.3.2	<p>Does this sample policy at least include:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Proper, full, and complete documentation, which shall include sample identification, the location, date and time of collection, collector's name, preservation type, sample type and any special remarks concerning the sample?</li> <li><input type="checkbox"/> Proper sample labeling to include unique identification and a labeling system for the samples with requirements concerning the durability of the labels (water resistant) and the use of indelible ink?</li> <li><input type="checkbox"/> Use of appropriate sample containers?</li> <li><input type="checkbox"/> Adherence to specified holding times?</li> <li><input type="checkbox"/> Adequate sample volume to perform the necessary tests?</li> <li><input type="checkbox"/> Procedures to be used when samples show signs of damage, contamination or inadequate preservation?</li> </ul>		
473	5.5.8.4	Does the laboratory have procedures and appropriate facilities for avoiding deterioration, contamination, loss or damage to the sample during storage, handling, preparation and testing?		
474	5.5.8.4	Does the laboratory follow any relevant instructions that may be provided with the test item?		
475	5.5.8.4	Are conditions be maintained, monitored and recorded when samples have to be stored or conditioned under specified environmental conditions?		

# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
476	5.5.8.4	Where a sample or a portion of a sample is to be held secure, does the laboratory have arrangements for storage and security that protect the condition and integrity of the secured samples or portions concerned?		
477	5.5.8.4.a	Are samples stored according to the conditions specified by preservation protocols?		
478	5.5.8.4.a.1	Are samples which require thermal preservation stored under refrigeration which is +/-2 of the specified preservation temperature unless method specific criteria exist?		
479	5.5.8.4.a.1	For samples with a specified storage temperature of 4°C, is storage at a temperature above the freezing point of water to 6°C considered acceptable?		
480	5.5.8.4.a.2	Are samples stored away from all standards, reagents, food and other potentially contaminating sources?		
481	5.5.8.4.a.2	Are samples stored in such a manner to prevent cross contamination?		
482	5.5.8.4.b	Are sample fractions, extracts, leachates and other sample preparation products stored according to 5.5.8.4.a above or according to specifications in the test method?		
483	5.5.8.4.b.1	Does the laboratory have SOPs for the disposal of samples, digestates, Leachates and extracts or other sample preparation products.		
484	5.5.9.1	Does the laboratory have quality control procedures for monitoring the validity of environmental tests undertaken?		
485	5.5.9.1	Are the data resulting from quality control procedures recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results?		
486	5.5.9.1.a-e	Is the quality control monitoring planned and reviewed? Note: it may include, but not limited to, the following: <ul style="list-style-type: none"> <li><input type="checkbox"/> Regular use of certified reference materials and/or internal quality control using secondary reference materials?</li> <li><input type="checkbox"/> Participation in interlaboratory comparison or proficiency-testing program? (see Chapter 2)</li> <li><input type="checkbox"/> Replicate tests or calibrations using the same or different methods?</li> <li><input type="checkbox"/> Retesting of retained samples?</li> <li><input type="checkbox"/> Correlation of results for different characteristics of a sample? (for example, total phosphate should be greater than or equal to orthophosphate)</li> </ul>		
487	5.5.9.2.a.1	Does the laboratory have detailed written protocols in place to monitor positive and negative controls to monitor tests such as blanks, spikes, reference toxicants?		

# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
488	5.5.9.2.a.2	Does the laboratory have detailed written protocols in place to monitor tests to define the variability and/or repeatability of the laboratory results such as replicates?		
489	5.5.9.2.a.3	Does the laboratory have detailed written protocols in place to monitor measures to assure the accuracy of the test method including calibration and/or continuing calibrations, use of certified reference materials, proficiency test samples, or other measures?		
490	5.5.9.2.a.4	Does the laboratory have detailed written protocols in place to monitor measures to evaluate test method capability, such as detection limits and quantitation limits or range of applicability such as linearity?		
491	5.5.9.2.a.5	Does the laboratory have detailed written protocols in place to monitor selection of appropriate formulae to reduce raw data to final results such as regression analysis, comparison to internal/external standard calculations, and statistical analyses?		
492	5.5.9.2.a.6	Does the laboratory have detailed written protocols in place to monitor selection and use of reagents and standards of appropriate quality?		
493	5.5.9.2.a.7	Does the laboratory have detailed written protocols in place to monitor measures to assure the selectivity of the test for its intended purpose?		
494	5.5.9.2.a.8	Does the laboratory have detailed written protocols in place to monitor measures to assure constant and consistent test conditions (both instrumental and environmental) where required by the test method such as temperature, humidity, light, or specific instrument conditions?		
495	5.5.9.2.b	Is quality control acceptance criteria used to determine the usability of the data?		
496	5.5.9.2.b	Are all quality control measures assessed and evaluated on an on-going basis?		
497	5.5.9.2.c	Does the laboratory have procedures for the development of acceptance/rejection criteria where no method or regulatory criteria exist?		
498	5.5.9.2.d	Are the quality control protocols specified by the laboratory's method manual (5.5.4.1.2) followed?		
499	5.5.9.2.d	Does the laboratory ensure that the essential standards outlined in Appendix D or mandated methods or regulations (whichever is more stringent) are incorporated into their method manuals?		
500	5.5.9.2.d	When it is not apparent which is more stringent is the QC in the mandated method or regulations followed?		

# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
501	5.5.10.1	Are the results of each test, or series of environmental tests carried out by the laboratory reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the environmental test methods?		
502	5.5.10.1	In the case of environmental tests or calibration results performed for internal clients, or in the case of a written agreement with the client, are the results reported in a simplified way?		
503	5.5.10.1	Is any information listed in 5.5.10.2 to 5.5.10.4 which is not reported to the client readily available in the laboratory which carried out the environmental tests results?		
504	5.5.10.1	Some regulatory reporting requirements or formats such as monthly operating reports may not require all items listed, in those cases does the laboratory provide all the required information to their client for use in preparing such regulatory reports?		
505	5.5.10.1	Are the results reported, usually in a test report, that includes all the information requested by the client and necessary for the interpretation of the environmental test results and all information required by the method used?		
506	5.5.10.1	Does the laboratory, if it is operated by a facility and whose sole function is to provide data to the facility management for compliance purposes (in-house or captive laboratories) have all applicable information specified in 5.5.10.2.a-m readily available for review by the accrediting authority?		
507	5.5.10.1	Does the facility management ensure that the appropriate report items are in the report to the regulatory authority if such information is required?		
508	5.5.10.2.a-e	<p>Does each test report include at least the following information unless the laboratory has valid reasons for not doing so, as indicated by 5.5.10.1.a and b?</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> A title (e.g. "Test Report," "Certificate of Results," or "Laboratory Results")?</li> <li><input type="checkbox"/> The name and address of the laboratory, the location where the environmental tests were carried out, if different from the address of the laboratory, and phone number with name of contact person for questions?</li> <li><input type="checkbox"/> Unique identification of the test report (such as the serial number), and on each page an identification in order to ensure that the page is recognized as a part of the test report?</li> <li><input type="checkbox"/> The name and address of the client and project name on the test reports?</li> <li><input type="checkbox"/> Identification of the method used?</li> </ul>		

# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
509	5.5.10.2.f	Does each test report include at least the following information unless the laboratory has valid reasons for not doing so, as indicated by 5.5.10.1.a and b? A description of, and unambiguous identification of; a description of, the condition of, and unambiguous identification of the sample(s), including the client identification code?		
510	5.5.10.2.g	Does each test report include at least the following information unless the laboratory has valid reasons for not doing so, as indicated by 5.5.10.1.a and b? The date of receipt of the sample(s) where this is critical to the validity and application of the results, date and time of sample collection, the date(s) of performance of the environmental test, and time of sample preparation and/or analysis if the required holding time for either activity is less than or equal to 72 hours?		
511	5.5.10.2.h	Does each test report include at least the following information unless the laboratory has valid reasons for not doing so, as indicated by 5.5.10.1.a and b? Reference to the sampling plan and procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results?		
512	5.5.10.2.i	Does each test report include at least the following information unless the laboratory has valid reasons for not doing so, as indicated by 5.5.10.1.a and b? The environmental test results with, where appropriate, the units of measurement, and any failures identified; identify whether data are calculated on a dry weight or wet weight basis; identify the reporting until such as ug/l or mg/kg; and for Whole Effluent Toxicity, identify the statistical package used to provide data;		
513	5.5.10.2.j	Does each test report include at least the following information unless the laboratory has valid reasons for not doing so, as indicated by 5.5.10.1.a and b? The name(s), function(s) and signatures or equivalent electronic identification of person(s) authorizing the test report, and date of issue?		
514	5.5.10.2.k	Does each test report include at least the following information unless the laboratory has valid reasons for not doing so, as indicated by 5.5.10.1.a and b? A statement to the effect that the results relate only to the samples?		
515	5.5.10.2.l	Does each test report include at least the following information unless the laboratory has valid reasons for not doing so, as indicated by 5.5.10.1.a and b? A statement that the certificate or report shall not be reproduced except in full, without the written approval of the laboratory?		



# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
516	5.5.10.2.m	Does each test report include at least the following information unless the laboratory has valid reasons for not doing so, as indicated by 5.5.10.1.a and b? Laboratories accredited to be in compliance with these standards shall certify that the test results meet all requirements of NELAC or provides reasons and/or justification if they do not?		
517	5.5.10.3.1.a-f	<p>Where it is necessary for the interpretation of the test results, does the test report also include the following:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Deviations from (such as failed quality control), additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions and any nonstandard conditions that may have affected the quality of results, including the use and definitions of data qualifiers?</li> <li><input type="checkbox"/> Where quality system requirements are not met, a statement of compliance/non-compliance with requirements and/or specifications, including identification of test results derived from any sample that did not meet NELAC sample acceptance requirements such as improper container, holding time, or temperature?</li> <li><input type="checkbox"/> Where applicable, a statement on the estimated uncertainty of measurement; information on uncertainty is needed when a client's instruction so requires?</li> <li><input type="checkbox"/> Where appropriate and needed, opinions and interpretations?</li> <li><input type="checkbox"/> Additional information which may be required by specific methods, clients or groups of clients?</li> <li><input type="checkbox"/> Qualification of numerical results with values outside of the working limits?</li> </ul>		
518	5.5.10.3.2.a-f	<p>Do test reports containing the results of sampling include the following, where necessary for the interpretation of test results:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> The date of sampling?</li> <li><input type="checkbox"/> Unambiguous identification of the substance, material or product sampled? (including the name of the manufacturer, the model or type of designation and serial numbers as appropriate);</li> <li><input type="checkbox"/> The location of sampling, including any diagrams, sketches or photographs?</li> <li><input type="checkbox"/> A reference to the sampling plan and procedures used?</li> <li><input type="checkbox"/> Details of any environmental conditions during sampling that may affect the interpretation of the test results?</li> <li><input type="checkbox"/> Any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned?</li> </ul>		

# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
519	5.5.10.4	When opinions and interpretations are included, does the laboratory document the basis upon which the opinions and interpretations have been made?		
520	5.5.10.4	Are opinions and interpretations clearly marked as such in a test report?		
521	5.5.10.5	Does the subcontractor report the results either in writing or electronically?		
522	5.5.10.5	Does the laboratory make a copy of the subcontractor's report available to the client when requested by the client?		
523	5.5.10.5	When the test report contains results of tests performed by subcontractors, are these results clearly identified by subcontractor name or applicable accreditation number?		
524	5.5.10.6	In the case of transmission of environmental test results by telephone, telex, facsimile or other electronic or electromagnetic means, are the requirements of this Standard met and ensure that all reasonable steps are taken to preserve confidentiality		
525	5.5.10.7	Is the format of the report designed to accommodate each type of environmental test carried out and to minimize the possibility of misunderstanding or misuse?		
526	5.5.10.8	Are material amendments to a test report after issue made only in the form of a further document, or data transfer, which includes the statement "Supplement to Test Report, serial number ... [or as otherwise identified]", or an equivalent form of wording?		
527	5.5.10.8	Do such test report amendments meet all the requirements of this Standard?		
528	5.5.10.8	When it is necessary to issue a complete new test report, is this uniquely identified and does it contain a reference to the original that it replaces?		

# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
<b>Appendix C – Demonstration of Capability</b>				
529	C.1	Is all data applicable to the Demonstration of Capability retained and available?		
530	C.1	In laboratories with specialized “work cells” (a well defined group of analysts that together perform the method analysis), does the group as a unit meet criteria and is the demonstration fully documented?		
531	C.1	Are all Demonstrations of Capability documented through the use of the form in this appendix?		
532	C.1	Is a Demonstration of Capability (DOC) made prior to using any test method? (see 5.5.4.2.2).		
533	C.1	When an analyte not currently found on the laboratory's list of accredited analytes is added to an existing accredited test method, is an initial evaluation performed for that analyte?		
534	C.1	Does the laboratory document that other approaches to DOC are adequate?		
535	C.1.a	If required by mandatory test method or regulation, does the laboratory obtain a quality control sample is from an outside source? If not available, the QC sample may be prepared by the laboratory using stock standards that are prepared independently from those used in instrument calibration?		
536	C.1.b	Are the analyte(s) diluted in a volume of clean quality system matrix sufficient to prepare four aliquots at the concentration specified or if unspecified, to a concentration of 1-4 times the limit of quantitation?		
537	C.1.c	Are at least four aliquots prepared and analyzed according to the test method either concurrently or over a period of days?		
538	C.1.d	Using all of the results, is the mean recovery calculated in the appropriate reporting units and the standard deviations of the population sample (n-1) (in the same units) for each parameter of interest?		
539	C.1.d	When it is not possible to determine mean and standard deviations, such as for presence/absence and logarithmic values, does the laboratory assess performance against established and documented criteria?		
540	C.1.e	Does the laboratory compare the information from (d) above to the corresponding acceptance criteria for precision and accuracy in the test method? (if applicable) or in laboratory-generated acceptance criteria? (if there are not established mandatory criteria)?		
541	C.1.e	Does the analysis of actual samples only begin if all parameters meet the acceptance criteria? Note: If any one of the parameters do not		

# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
		meet the acceptance criteria, the performance is unacceptable for that parameter.		
542	C.1.f.1-2	When one or more of the tested parameters fail at least one of the acceptance criteria, does the analyst locate and correct the source of the problem and repeat the DOC for all parameters of interest?		
543	C.2	Is a copy of the certification statement retained in the personnel records of each affected employee?		
544	C.3.1.a	Does the laboratory determine the Limit of Detection (LOD) for the method for each target analyte of concern in the quality system matrices?		
545	C.3.1.a	Do all sample-processing steps of the analytical method include the determination of the LOD?		
546	C.3.1.b	Is the validity of the LOD confirmed by qualitative identification of the analyte(s) in a QC sample in each quality system matrix containing the analyte at no more than 2-3 X the LOD for single analyte tests and 1-4 X the LOD for multiple analyte tests?		
547	C.3.1.b	Is this verification performed on every instrument that is to be used for analysis of samples and reporting of data?		
548	C.3.1.c	Where an LOD study is not performed, does the laboratory not report a value below the Limit of Quantitation?		
549	C.3.2.a	Does the laboratory determine the Limit of Quantitation (LOQ) for each analyte of concern according to a defined, documented procedure? Note: the LOQ study is not required for any component or property for which spiking solutions or quality control samples are not commercially available or otherwise inappropriate (e.g., pH).		
550	C.3.2.c	Is the validity of the LOQ confirmed by successful analysis of a QC sample containing the analytes of concern in each in each quality system matrix 1-2 times the claimed LOQ? Note: a successful analysis one where the recovery of each analyte is within the established test method acceptance criteria or client data quality objectives for accuracy. This single analysis is not required if the bias and precision of the measurement system is evaluated at the LOQ.		
551	C.3.3.a	When using Standard methods, does the laboratory evaluate the Precision and Bias of a Standard Method for each analyte of concern for each quality system matrix according to the single-concentration four-replicate recovery study procedures in Appendix C.1 above (or alternate procedure documented in the quality manual when the analyte cannot be spiked into the sample matrix and QC samples are not commercially available)?		
552	C.3.3.b	When using Non-Standard methods for Laboratory-developed test		

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No	Reference	Question	Y-N-N/A	Comments
		methods or non-standard test methods as defined at 5.5.4.3 and 5.5.4.4. that were not in use by the laboratory before July 2003, did the laboratory document procedure to evaluate precision and bias?		
553	C.3.3.b	Does the laboratory compare results of the precision and bias measurements with criteria established by the client, by criteria given in the reference method or criteria established by the laboratory?		
554	C.3.3.b	Do the precision & bias measurements evaluate the laboratory-developed or non-standard test method across the analytical calibration range of the method?		
555	C.3.3.b	Do the precision and bias measurements evaluate the laboratory-developed or non-standard test method across the analytical calibration range of the method? Note: Examples of systemic approach to evaluate precision & bias could be: (i) a validation protocol, such as the Tier I, Tier II, and Tier III requirements in US EPA Office of Water's Alternate Test Procedure (ATP) approval process, or (ii) replicate analysis of quality control samples at or near the LOQ, at the upper range of the calibration, & at a mid-range concentration, processed on different days as 3 sets of samples through the entire measurement system for each analyte of interest (see Appendix C.3.3(b) to NELAC Chapter 5 for further details)."		
556	C.4	Does the laboratory evaluate selectivity by following the checks established within the method? Note: This may include mass spectral tuning, second column confirmation, ICP inter-element interference checks, chromatography retention time windows, sample blanks, spectrochemical absorption or fluorescence profiles, co-precipitation evaluations, and electrode response factors.		

# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
<b>Appendix D – Essential Quality Control Requirements</b>				
557	Appendix D	Does the laboratory ensure that the essential standards outlined in Appendix D are incorporated into their method manuals and/or the Laboratory Quality Manual?		
558	Appendix D	Are all quality control measures assessed and evaluated on an on-going basis?		
559	Appendix D	Are quality control acceptance criteria used to determine the validity of the data.		
560	Appendix D	Does the laboratory have procedures for the development of acceptance/rejection criteria where no method or regulatory criteria exists?		
561	Appendix D	Are the quality control protocols specified by the laboratory's method manual (5.5.4.1.2) followed?		

# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
<b>Appendix D.1 – Chemical Testing</b>				
562	D.1.1.1.a	Is the method blank processed along with and under the same conditions as the associated samples including all steps of the analytical procedure?		
563	D.1.1.1.a	Are procedures in place to determine if a method blank is contaminated?		
564	D.1.1.1.a	Is any affected sample associated with a contaminated method blank reprocessed for analysis or the results reported with appropriate data qualifying codes?		
565	D.1.1.1.b	Is the method blank analyzed at a minimum of 1 per preparation batch?		
566	D.1.1.1.b	In those instances for which no separate preparation method is used (example: volatiles in water) is the batch defined as environmental samples that are analyzed together with the same method and personnel, using the same lots of reagents, not to exceed the analysis of 20 environmental samples?		
567	D.1.1.1.c	Does the method blank consist of a matrix that is similar to the associated samples known to be free of the analytes of interest?		
568	D.1.1.1.d	Is each method blank critically evaluated as to the nature of the interference and the effect on the analysis of each sample within the batch?		
569	D.1.1.1.d	Is the source of blank contamination investigated and measures taken to minimize or eliminate the problem?		
570	D.1.1.1.d.1	Are samples affected by blank contamination reprocessed or is the data appropriately qualified if the concentration of a targeted analyte in the blank is at or above the reporting limit as established by the test method or by regulation, AND is greater than 1/10 of the amount measured in any sample?		
571	D.1.1.1.d.2	Are samples affected by blank contamination reprocessed or is the data appropriately qualified if the blank contamination otherwise affects the sample results as per the test method requirements or the individual project data quality objectives?		
572	D.1.1.1.d.3	When a blank is determined to be contaminated, does the laboratory investigate the cause and take measures taken to minimize or eliminate the problem?		
573	D.1.1.1.d.3	Does the laboratory evaluate samples associated with a contaminated blank as to the best corrective action for the samples (e.g. reprocessing or data qualifying codes) and is the corrective action documented?		

# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
574	D.1.1.2.1.b	Is the LCS analyzed at a minimum of 1 per preparation batch? (Exceptions would be for those analytes for which no spiking solutions are available such as total suspended solids, total dissolved solids, total volatile solids, total solids, pH, color, odor, temperature, dissolved oxygen or turbidity)		
575	D.1.1.2.1.b	In those instances for which no separate preparation method is used (example: volatiles in water) is the batch defined as environmental samples that are analyzed together with the same method and personnel, using the same lots of reagents, not to exceed the analysis of 20 environmental samples?		
576	D.1.1.2.1.c	If the matrix spike is used in place of the LCS are the acceptance criteria as stringent as for the LCS?		
577	D.1.1.2.1.a	Is the LCS used to evaluate the performance of the total analytical system, including all preparation and analysis steps? Note: The LCS is a controlled matrix, known to be free of analytes of interest, spiked with known and verified concentrations of analytes. Alternatively the LCS may consist of a media containing known and verified concentrations of analytes or as Certified Reference Material (CRM)		
578	D.1.1.2.1.c	Does the laboratory insure that all targeted components are included in the LCS spike mixture over a 2 year period?		
579	D.1.1.2.1.c	Are all analyte concentrations in the LCS within the calibration range of the methods?		
580	D.1.1.2.1.c	Are all the components spiked in the LCS as specified by the mandated test method or other regulatory requirement or as requested by the client?		
581	D.1.1.2.1.c	For those components that interfere with an accurate assessment such as spiking simultaneously with technical chlordane, toxaphene and PCBs, is the spike for the LCS chosen to represent the chemistries and elution patterns of the components to be reported?		
582	D.1.1.2.1.c	For those test methods that have extremely long lists of analytes, is a representative number chosen for the LCS?		
583	D.1.1.2.1.c	For methods that include 1-10 targets, are all components spiked in the LCS?		
584	D.1.1.2.1.c	For methods that include 11-20 targets, are at least 10 or 80%, whichever is greater components spiked in the LCS?		
585	D.1.1.2.1.c	For methods with more than 20 targets, are at least 16 components spiked in the LCS?		
586	D.1.1.2.1.a	Are results of the LCS compared to established criteria?		
587	D.1.1.2.1.d	Are the results of the individual batch LCS calculated in percent		



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No	Reference	Question	Y-N-N/A	Comments
		recovery or other appropriate statistical technique that allows comparison to established acceptance criteria?		
588	D.1.1.2.1.d	Does the laboratory document the statistical calculation for the LCS?		
589	D.1.1.2.1.d	Is the individual LCS compared to the acceptance criteria as published in the mandated test method?		
590	D.1.1.2.1.d	Where there are no established criteria for the LCS, does the laboratory determine internal criteria and document the method used to establish the limits or utilize client specified assessment criteria?		
591	D.1.1.2.1.a	If the LCS is found to be outside of these criteria, is the analytical system considered "out of control"?		
592	D.1.1.2.1.a	Are any affected samples associated with an out of control LCS reprocessed for re-analysis or the results reported with appropriate data qualifying codes?		
593	D.1.1.2.1.d	Are samples analyzed along with a LCS determined to be "out of control" considered suspect and the samples reprocessed and re-analyzed or the data reported with appropriate data qualifying codes?		
594	D.1.1.2.1.e	Are the number of allowable marginal exceedences determined as follows: <input type="checkbox"/> >90 analytes in LCS, no more than 5 analytes allowed in ME of the LCS control limit? <input type="checkbox"/> 71-90 analytes in LCS, no more than 4 analytes allowed in ME of the LCS control limit? <input type="checkbox"/> 51-70 analytes in LCS, no more than 3 analytes allowed in ME of the LCS control limit? <input type="checkbox"/> 31-50 analytes in LCS, no more than 2 analytes allowed in ME of the LCS control limit? <input type="checkbox"/> 11-30 analytes in LCS, no more than 1 analytes allowed in ME of the LCS control limit? <input type="checkbox"/> <11 analytes in LCS, no analytes allowed in ME of the LCS control limit?		
595	D.1.1.2.1.e	Are the LCS marginal exceedences random?		
596	D.1.1.2.1.e	If the same analyte exceeds the LCS control limit repeatedly, it is an indication of a systemic problem. Is the source of the error located and corrective action taken?		
597	D.1.1.2.1.e	Do laboratories have a written procedure to monitor the application of marginal exceedence allowance to the LCS to ensure random behavior?		
598	D.1.1.3	Does the laboratory document procedures for determining the effect of the sample matrix on method performance? Note: These controls alone are not used to judge laboratory performance. Examples of		

# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
		matrix specific QC include: Matrix Spike (MS); Matrix Spike Duplicate (MSD); sample duplicates; and surrogate spikes.		
599	D.1.1.3	Does the laboratory have procedures in place for tracking, managing, and handling matrix specific QC criteria including spiking appropriate components at appropriate concentrations, calculating recoveries and relative percent difference, evaluating and reporting results based on performance of the QC samples? Note: Matrix specific QC samples indicate the effect of the sample matrix on the precision and accuracy of the results generated using the selected method. The information from these controls is sample/matrix specific and would not normally be used to determine the validity of the entire batch.		
600	D.1.1.3.1.b	Is the frequency of the analysis of matrix specific samples determined as part of a systematic planning process (e. g. Data Quality Objectives) or as specified by the required mandated test method?		
601	D.1.1.3.1.c	Do the components in the matrix spike include those specified by the mandated test method?		
602	D.1.1.3.1.c	Are any permit specified analytes, as specified by regulation or client requested analytes also included in the matrix spike?		
603	D.1.1.3.1.c	For those components that interfere with an accurate assessment of the matrix spike, such as spiking simultaneously with technical chlordane, toxaphene and PCBs, is the spike chosen to represent the chemistries and elution patterns of the components to be reported? (Recommendation)		
604	D.1.1.3.1.c	For those test methods that have extremely long lists of analytes, a representative number may be chosen. Are the analytes selected for the matrix spike representative of all analytes reported? (Recommendation)		
605	D.1.1.3.1.c	Does the laboratory insure that all targeted components are included in the matrix spike mixture over a 2 year period?		
606	D.1.1.3.1.c.1	For methods that include 1-10 targets, are all components spiked in the matrix spike?		
607	D.1.1.3.1.c.2	For methods that include 11-20 targets, are at least 10 or 80%, whichever is greater, spiked in the matrix spike?		
608	D.1.1.3.1.c.3	For methods with more than 20 targets, are at least 16 components spiked in the matrix spike?		
609	D.1.1.3.1.d	Are the results from matrix spike/matrix expressed as percent recovery (%R), relative percent difference (RPD) or other appropriate statistical technique that allows comparison to established acceptance criteria?		
610	D.1.1.3.1.d	Does the laboratory document the calculation for %R, RPD or other statistical treatment used in the matrix spike?		

# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
611	D.1.1.3.1.d	Are the results of the matrix spike compared to the acceptance criteria as published in the mandated test method?		
612	D.1.1.3.1.d	Where there are no established criteria for the matrix spike, does the laboratory determine internal criteria and document the method used to establish the limits?		
613	D.1.1.3.1.d	Are matrix spike results outside established criteria corrective action documented or is the data reported with appropriate data qualifying codes?		
614	D.1.1.3.2.b	Is the frequency of the analysis of matrix duplicates determined as part of a systematic planning process (e. g. Data Quality Objectives) or as specified by the mandated test method?		
615	D.1.1.3.2.c	Are matrix duplicates performed on replicate aliquots of actual samples?		
616	D.1.1.3.2.d	Does the laboratory document the calculation for relative percent difference or other statistical treatments for the matrix duplicate?		
617	D.1.1.3.2.d	Are results of the matrix duplicate compared to the acceptance criteria as published in the mandated test method?		
618	D.1.1.3.2.d	Where there are no established criteria, does the laboratory determine internal criteria and document the method used to establish the limits for matrix duplicate?		
619	D.1.1.3.2.d	For matrix duplicate results outside established criteria, is corrective action documented or the data reported with appropriate data qualifying codes?		
620	D.1.1.3.3.b	Except where the matrix precludes its use or when not commercially available, are surrogate compounds added to all samples, standards, and blanks for all appropriate test methods? Note: Surrogates are used most often in organic chromatography test methods and are chosen to reflect the chemistries of the targeted components of the method and added prior to sample preparation/ extraction, do they provide a measure of recovery for every sample matrix.		
621	D.1.1.3.3.d	Are the results of the surrogates compared to the acceptance criteria as published in the mandated test method?		
622	D.1.1.3.3.d	Where there are no established criteria for surrogates, does the laboratory determine internal criteria and document the method used to establish the limits? (Recommendation)		
623	D.1.1.3.3.d	Are surrogates outside the acceptance criteria evaluated for the effect indicated for the individual sample results?		
624	D.1.1.3.3.d	Is the corrective action for surrogate failure guided by the data quality objectives or other site specific requirements? (Recommendation)		

# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
625	D.1.1.3.3.d	Do results reported from analyses with surrogate recoveries outside the acceptance criteria include appropriate data qualifiers? (Recommendation)		
626	D.1.2	Are all procedures used to determine Limit of Detection documented, including the quality system matrix type and all supporting data?		
627	D.1.2.1	Does the laboratory utilize test methods that provide a detection limit that is appropriate and relevant for the intended use of the data?		
628	D.1.2.1	Are LODs determined by the protocol in the mandated test method or applicable regulation.		
629	D.1.2.1	If the protocol for determining detection limits is not specified, does the selection of the procedure reflect instrument limitations and the intended application of the test method?		
630	D.1.2.1.a	Is the LOD initially determined for the compounds of interest in each test method in a quality system matrix in which there are not target analytes nor interferences at a concentration that would impact the results or is the LOD determined in the quality system matrix of interest (see definition of matrix)?		
631	D.1.2.1.b	Are LODs determined each time there is a change in the test method that affects how the test is performed, or when a change in instrumentation occurs that affects the sensitivity of the analysis?		
632	D.1.2.1.c	Does the laboratory have established procedures to relate LOD with LOQ?		
633	D.1.2.1.d	Is the LOD verified annually for each quality system matrix, method and analyte according to the procedure specified in C.3?		
634	D.1.2.2.a	Are any established LOQ above the LOD?		
635	D.1.2.2.b	Is the LOQ verified annually for each quality matrix, method and analyte according to the procedure specified in C.3?		
636	D.1.3	Are the procedures for data reduction, such as use of linear regression documented?		
637	D.1.4.a	Do the source standards comply with 5.5.6.2.2.2?		
638	D.1.4.b	In methods where the purity of reagents is not specified, is analytical reagent grade used?		
639	D.1.4.b.1	Are reagents of lesser purity than those specified by the test method never used?		
640	D.1.4.b.1	Are the labels on the container checked to verify that the purity of the reagents meets the requirements of the particular test method? (Recommendation)		
641	D.1.4.b.1	Does the laboratory document the checks to verify that the purity of the		

# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
		reagents meets the requirements of the particular test method?		
642	D.1.4.b.2	Is the quality of water sources monitored and documented?		
643	D.1.4.b.2	Does the quality of water sources meet method specified requirements?		
644	D.1.4.b.3	Does the laboratory verify the concentration of titrants in accordance with written laboratory procedures?		
645	D.1.5.a	Does the laboratory evaluate selectivity by following the checks established within the method, which may include mass spectral tuning, second column confirmation, ICP interelement interference checks, chromatography retention time windows, sample blanks, spectrochemical absorption or fluorescence profiles, co-precipitation evaluations, and electrode response factors?		
646	D.1.5.b	Is a confirmation performed to verify the compound identification when positive results are detected on a sample from a location that has not been previously tested by the laboratory?		
647	D.1.5.b	Are confirmations performed on organic tests such as pesticides, herbicides, or acid extractable or when recommended by the analytical test method except when the analysis involves the use of a mass spectrometer?		
648	D.1.5.b	Is confirmation performed unless stipulated in writing by the client?		
649	D.1.5.b	Are all confirmations documented?		
650	D.1.5.c	Does the laboratory document acceptance criteria for mass spectral tuning?		
651	D.1.6.a	Does the laboratory assure that the test instruments consistently operate within the specifications required of the application for which the equipment is used?		
652	D.1.6.b	Is glassware cleaned to meet the sensitivity of the test method?		
653	D.1.6.b	Are any cleaning and storage procedures not specified by the test method documented in laboratory records and SOPs?		

NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
<b>Appendix D.3 – Microbiology Testing</b>				
752	D.3.1.a	Does the laboratory demonstrate that the filtration equipment and filters, sample containers, media and reagents have not been contaminated through improper handling or preparation, inadequate sterilization, or environmental exposure?		
753	D.3.1.a.1	Is a sterility blank analyzed for each lot of pre-prepared, ready-to-use medium (including chromofluorogenic reagent) or batch of medium prepared in the lab prior to the first use of the medium?		
754	D.3.1.a.2	For each filtration series in the filtration technique, does the laboratory prepare one beginning and one ending sterility check for each laboratory sterilized unit prior to beginning the series or, for pre-sterilized single-use funnels, one per lot?		
755	D.3.1.a.2	When an interruption of more than 30 minutes occurs, are the filtration funnels re-sterilized?		
756	D.3.1.a.2	Are filtration units rinsed with three 20-30 mL portions of sterile rinse water after each sample filtration?		
757	D.3.1.a.2	Does the laboratory insert a sterility blank after every 10 samples or sanitize filtration units by UV light after each sample filtration?		
758	D.3.1.a.3	For pour plate technique, are sterility blanks of the medium made by pouring, at a minimum, one uninoculated plate for each lot of pre-prepared, ready-to-use media and for each batch of medium prepared in the laboratory?		
759	D.3.1.a.4	Are sterility checks on sample containers performed on at least one container for each lot of purchased, pre-sterilized containers?		
760	D.3.1.a.4	For sample containers prepared and sterilized in the laboratory, is a sterility check performed on one container per sterilized batch with non-selective growth media?		
761	D.3.1.a.5	Is a sterility blank performed on each batch of dilution water prepared in the laboratory and on each batch of pre-prepared, ready-to-use dilution water with non-selective growth media?		
762	D.3.1.a.6	Is at least one filter from each new lot of membrane filters checked for sterility with non-selective growth media?		
763	D.3.1.b.1	Is each lot of pre-prepared, ready-to-use medium (including chromofluorogenic reagent) and each batch of medium prepared in the laboratory tested with at least one pure culture of a known positive reaction prior to first use of the medium?		
764	D.3.1.c	Is each pre-prepared, ready-to-use lot of selective medium (including chromofluorogenic reagent) and each batch of selective medium prepared in the laboratory analyzed with one or more known negative		

# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
		culture controls, i.e. non-target organisms, as appropriate to the method prior to first use?		
765	D.3.2	For test methods that specify colony counts such as membrane filter or plated media, are duplicate counts performed monthly on one positive sample, for each month that the test is performed?		
766	D.3.2	If the lab has two or more analysts, does each analyst count typical colonies on the same plate for each month the test is performed?		
767	D.3.2	Are duplicate counts by different analysts considered to be acceptable only if the difference is within 10%?		
768	D.3.2	In a laboratory with only one microbiology analyst, is the same plate counted twice by the analyst for each month the test is performed?		
769	D.3.2	Are duplicate counts by the same analyst considered to be acceptable only if the difference is within 5%?		
770	D.3.3.a	Does the laboratory demonstrate proficiency with the test method prior to first use by comparison to a method already approved for use in the laboratory, or by analyzing a minimum of ten spiked samples whose matrix is representative of those normally submitted to the laboratory, or by analyzing and passing one proficiency test series provided by an approved proficiency sample provider?		
771	D.3.3.a	Does the laboratory maintain the method evaluation documentation as long as the method is in use and for at least 5 years past the date of last use?		
772	D.3.3.b	Does the laboratory participate in the Proficiency Test programs (inter-laboratory) identified by NELAP to evaluate the ability of the laboratory to produce acceptable data?		
773	D.3.4.a	Are all growth and recovery media checked to assure that the target organisms respond in an acceptable and predictable manner?		
774	D.3.4.b	To ensure that analysis results are accurate, is target organism identity verified as specified in the method, e.g. by use of the completed test, or by use of secondary verification tests such as a catalase test?		
775	D.3.5	Are the calculations, data reduction, and statistical interpretations specified by each method followed?		
776	D.3.6	Does the laboratory ensure that the quality of the reagents and media used is appropriate for the test concerned?		
777	D.3.6.a	Is culture media prepared in the laboratory from commercial dehydrated powders, purchased ready to use, or prepared from basic ingredients if not available commercially or when it can be demonstrated that commercial media do not provide adequate results?		
778	D.3.6.a	Are media prepared by the laboratory from basic ingredients tested for		

# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
		performance (e.g. for selectivity, sensitivity, sterility, growth promotion, growth inhibition) prior to first use?		
779	D.3.6.a	Are detailed testing criteria information defined in either the laboratory's test methods, SOPs, Quality Manual, or similar documentation?		
780	D.3.6.b	Are reagents, commercial dehydrated powders, and media used within the shelf life of the product and documented according to 5.5.6.4?		
781	D.3.6.c	Is distilled water, deionized water, or reverse osmosis produced water free from bactericidal and inhibitory substances used in the preparation of media solutions and buffers?		
782	D.3.6.c	Is the quality of the water monitored for chlorine residual, specific conductance, and heterotrophic bacteria plate count on a monthly frequency (when in use), when maintenance is performed on the water treatment system, and at startup after a period of disuse longer than one month?		
783	D.3.6.c	Are the analyses for metals and the Bacteriological Water Quality Test (to determine presence of toxic agents or growth promoting substances) performed annually?		
784	D.3.6.c	For an exception to the annual performance of the Bacteriological Water Quality Test, does the laboratory document that their water source meets the criteria, as specified by the method, for Type I or Type II reagent water?		
785	D.3.6.c	Do the results of these analyses meet the specifications of the required method and are records of analyses maintained for five years?		
786	D.3.6.d	Are media, solutions, and reagents prepared, used and stored according to a documented procedure following the manufacturer's instructions or the test method?		
787	D.3.6.d	Does documentation for media prepared in the laboratory include: <ul style="list-style-type: none"> <li><input type="checkbox"/> Date of preparation?</li> <li><input type="checkbox"/> Preparer's initials?</li> <li><input type="checkbox"/> Type and amount of media prepared?</li> <li><input type="checkbox"/> Manufacturer and lot number?</li> <li><input type="checkbox"/> Final pH of the media?</li> <li><input type="checkbox"/> Expiration date?</li> </ul>		
788	D.3.6.d	Does documentation for media purchased pre-prepared, ready-to-use include: <ul style="list-style-type: none"> <li><input type="checkbox"/> Manufacturer?</li> <li><input type="checkbox"/> Lot number?</li> <li><input type="checkbox"/> Type and amount of media received?</li> <li><input type="checkbox"/> Date of receipt?</li> </ul>		



# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
		<input type="checkbox"/> Expiration date of the media? <input type="checkbox"/> pH of the media?		
789	D.3.7.a	In order to ensure identity and traceability, does the laboratory use reference cultures for positive and negative control culture microorganisms obtained from a recognized national collection, organization, or manufacturer recognized by the NELAP Accrediting Authority?		
790	D.3.7.a	Are microorganisms single use preparations or cultures maintained by documented procedures that demonstrate the continued purity and viability of the organism?		
791	D.3.7.a.1	Are reference cultures revived (if freeze-dried) or transferred from slants and sub-cultured once to provide reference stocks?		
792	D.3.7.a.1	Are the reference stocks preserved by a technique that maintains the desired characteristics of the strains?		
793	D.3.7.a.1	Are reference stocks used to prepare working stocks for routine work?		
794	D.3.7.a.1	Does the laboratory not re-freeze or re-use reference stocks after they are thawed?		
795	D.3.7.a.2	Are working stocks sub-cultured no more than 5 times?		
796	D.3.7.a.2	Are working stocks not sub-cultured to replace reference stocks?		
797	D.3.8.a	Are walls, floors, ceilings, and work surfaces non-absorbent and easy to clean and disinfect?		
798	D.3.8.a	Are work surfaces adequately sealed?		
799	D.3.8.a	Does the laboratory provide sufficient storage space?		
800	D.3.8.a	Is the laboratory clean and free from dust accumulation?		
801	D.3.8.a	Does the laboratory prohibit plants, food, and drink in the laboratory work area?		
802	D.3.8.b.1	Are the temperature measurement devices such as liquid-in-glass thermometers, thermocouples, and platinum resistance thermometers used in incubators, autoclaves, and other equipment of the appropriate quality needed to meet the specification in the test method?		
803	D.3.8.b.1	Are the graduations of the temperature measuring devices appropriate for the required accuracy of measurement?		
804	D.3.8.b.1	Are temperature measuring devices calibrated to national or international standards at least annually?		
805	D.3.8.b.2.i	Is the performance of each autoclave initially evaluated by establishing its functional properties and performance, for example heat distribution characteristics with respect to typical uses?		

# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
806	D.3.8.b.2.i	Do autoclaves meet specified temperature tolerances?		
807	D.3.8.b.2.i	Are pressure cookers not used for sterilization of growth media?		
808	D.3.8.b.2.ii	Is sterilization temperature demonstrated by the use of a continuous temperature recording device or through the use of a maximum registering thermometer with every cycle?		
809	D.3.8.b.2.ii	Are appropriate biological indicators used at least once each month of use to determine effective sterilization?		
810	D.3.8.b.2.ii	Is temperature sensitive tape used with the contents of each autoclave run to indicate that the autoclave contents have been processed?		
811	D.3.8.b.2.iii	Are records of autoclave operations maintained and include for each cycle: Date, contents, maximum temperature reached, pressure, time in sterilization mode, total run time (may be recorded as time in and time out) and analysts initials?		
812	D.3.8.b.2.iv	Is autoclave maintenance performed annually either internally or by service contract?		
813	D.3.8.b.2.iv	Does the annual maintenance of the autoclave include a pressure check and calibration of temperature device?		
814	D.3.8.b.2.iv	Are records of the maintenance of the autoclave maintained in equipment logs?		
815	D.3.8.b.2.v	Is the autoclave mechanical timing device checked quarterly against a stopwatch and is the actual time elapsed documented?		
816	D.3.8.b.3.i-iii	Is volumetric equipment calibrated as follows: <input type="checkbox"/> Equipment with movable parts such as automatic dispensers, dispensers/diluters, and mechanical hand pipettes shall be verified for accuracy quarterly? <input type="checkbox"/> Equipment such as filter funnels, bottles, non-class A glassware, and other marked containers calibrated once per lot prior to first use? <input type="checkbox"/> The volume of the disposable volumetric equipment such as sample bottles, disposable pipettes, and micropipette tips checked once per lot?		
817	D.3.8.b.4	Are UV instruments, used for sanitization, tested quarterly for effectiveness with an appropriate UV light meter or by plate count agar spread plates?		
818	D.3.8.b.4	For UV instruments, used for sanitation, are bulbs replaced if output is less than 70% of original for light tests or if count reduction is less than 99% for a plate containing 200 to 300 organisms?		
819	D.3.8.b.5	Is support equipment calibrated according to the method specified requirements? (Note this includes conductivity meters, oxygen meters,		

# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
		pH meters, hygrometers, and other similar measurement instruments)		
820	D.3.8.b.6.i	Has the stability and uniformity of temperature distribution and time after test sample addition required to re-establish equilibrium conditions in incubators and water baths been established?		
821	D.3.8.b.6.i	Is the temperature of incubators and water baths documented twice daily, at least four hours apart, on each day of use?		
822	D.3.8.b.6.ii	Are ovens used for sterilization checked for sterilization effectiveness monthly with appropriate biological indicators?		
823	D.3.8.b.6.ii	Do records maintained for each oven sterilization cycle include: <input type="checkbox"/> Date? <input type="checkbox"/> Cycle time? <input type="checkbox"/> Temperature? <input type="checkbox"/> Contents? <input type="checkbox"/> Analyst's initials?		
824	D.3.8.b.7.i	Does the laboratory have a documented procedure for washing labware, if applicable?		
825	D.3.8.b.7.i	Does the laboratory use detergents designed for laboratory use?		
826	D.3.8.b.7.ii	Is glassware made of borosilicate or other non-corrosive material, free of chips and cracks, and does it have readable measurement marks?		
827	D.3.8.b.7.iii	Does the laboratory test glassware for possible presence of residues which may inhibit or promote growth of microorganisms by performing the Inhibitory Residue Test annually, and each time the lab changes the lot of detergent or washing procedures?		
828	D.3.8.b.7.iv	Is washed glassware tested at least one daily, each day of washing, for possible acid or alkaline residue by testing one piece of glassware with a suitable pH indicator such as bromthymol blue, with a record of the test being maintained?		

# NELAC Quality Systems

No	Reference	Question	Y-N-N/A	Comments
		INTERNAL AUDITS		
		MANAGEMENT REVIEWS		
		COMPLAINT		
		PERSONNEL FILES		
		PROFICIENCY TESTING		
		DATA REVIEW		
		QUALITY MANUAL		
		SOP		
		MDL/LOD/LOQ		
		WATER SYSTEM		
		SAMPLE RESEAVING		
		EQUIPMENT		
		STANDARD AND REAGENTS		